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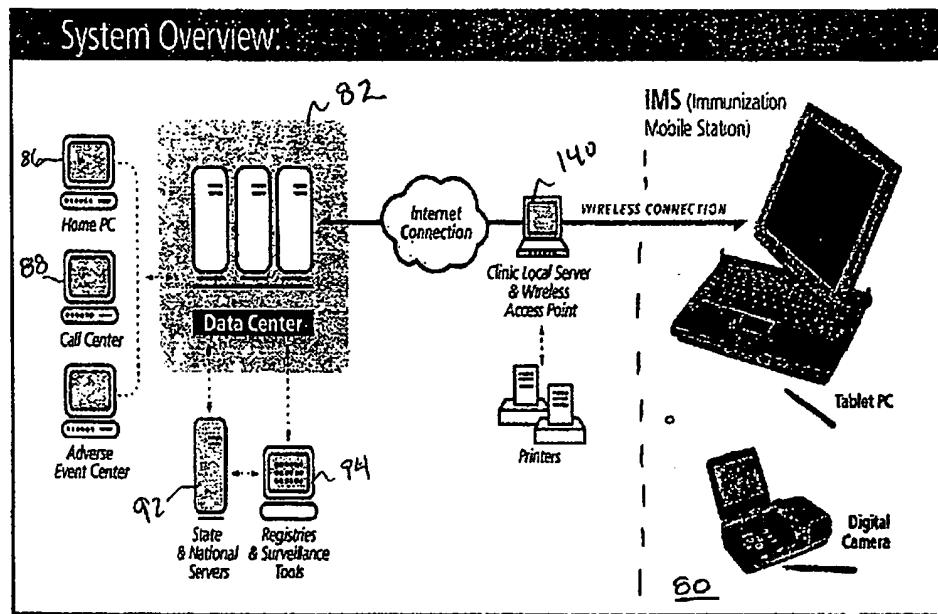
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(54) Titre : SYSTEME DE COLLECTE, DE STOCKAGE, DE PRESENTATION ET D'ANALYSE DE DONNEES DE VACCINATION DANS LEQUEL DES STATIONS ELOIGNEES COMMUNIQUENT AVEC UNE BASE DE DONNEES DE VACCINATION ET DES MALADIES AU SEIN D'UN RESEAU
 (54) Title: SYSTEM FOR COLLECTING, STORING, PRESENTING AND ANALYZING IMMUNIZATION DATA HAVING REMOTE STATIONS IN COMMUNICATION WITH A VACCINE AND DISEASE DATABASE OVER A NETWORK



(57) Abrégé/Abstract:

Immunization mobile stations (IMSs 80) collect patient information such as biographical data, previous vaccination data, medical history, medications in use, occupation, administration of recent vaccination, and disease symptoms. IMSs 80 synchronize the patient information with information stored in a database 116 at a center 82 that is accessible to different groups of personnel based on different privileges and security measures. Patients can access electronic patient records created by the IMSs, and stored at the IMSs and/or a local server 140 and eventually at the data center, via telephone or computer (e.g., via web browser). IMSs can capture and store images of vaccination and disease symptom sites on patients. The database 116 allows for vaccination and disease tracking and disease control. IMSs 80 have vaccination recommendation engine, electronic patient consent forms, and are programmable to track adverse events and create follow-up reports after a vaccine is administered.

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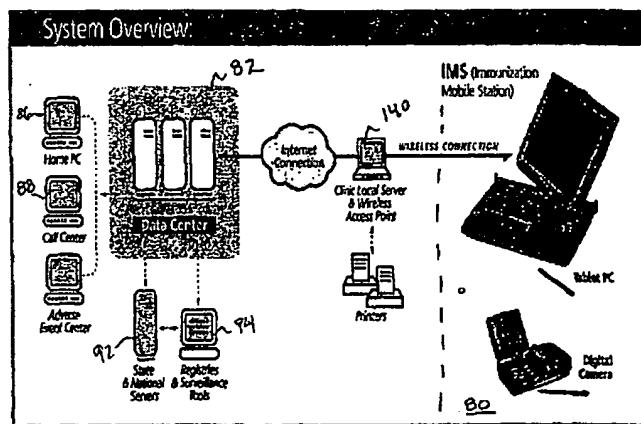
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(57) Abstract: Immunization mobile stations (IMSSs 80) collect patient information such as biographical data, previous vaccination data, medical history, medications in use, occupation, administration of recent vaccination, and disease symptoms. IMSSs 80 synchronize the patient information with information stored in a database 116 at a center 82 that is accessible to different groups of personnel based on different privileges and security measures. Patients can access electronic patient records created by the IMSSs, and stored at the IMSSs and/or a local server 140 and eventually at the data center, via telephone or computer (e.g., via web browser). IMSSs can capture and store images of vaccination and disease symptom sites on patients. The database 116 allows for vaccination and disease tracking and disease control. IMSSs 80 have vaccination recommendation engine, electronic patient consent forms, and are programmable to track adverse events and create follow-up reports after a vaccine is administered.

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**SYSTEM FOR COLLECTING, STORING, PRESENTING AND ANALYZING
IMMUNIZATION DATA HAVING REMOTE STATIONS IN COMMUNICATION WITH
A VACCINE AND DISEASE DATABASE OVER A NETWORK**

Field Of The Invention

[0001] The present invention relates generally to a computer-based information system for conducting, over an electronic network such as the Internet, the transmission of medical information including information pertaining to immunization administrations, adverse events and side effects information records.

Background Of The Invention

Immunization Market Overview

[0002] The United States immunization industry had over \$5 billion in annual revenue in 2000 and is expected to grow at a rate exceeding 10% per year through 2010. The monetary value of the market consists of vaccine delivery devices (around \$60 million annually), vaccines (around \$2 billion) and vaccine administration (around \$3 billion). Additional value derives from lifestyle benefits to consumers (e.g., due to reduced illness), employee productivity gains, and from synergy value to point of care and providers (e.g., enhanced loyalty and the value of new customers for pharmacy chains). The growth potential of the vaccine industry is focused on transferring value from these last two layers to the layers of vaccines and vaccine administration. The factors underlying this expected growth include a large pipeline of preventive and therapeutic vaccines introduced to the market at premium prices.

[0003] The immunization market value chain is consistent of various value-added layers. A need exists for a system such as the present invention disclosed below that can address each one of the layers in the immunization market value chain.

Concentrated Manufacturing and Distribution

[0005] The vaccine manufacturing industry is highly concentrated with more than 75% of the vaccine manufacturing produced by four firms (i.e., Merck & Co., Inc., Glaxo Smithkline, Wyeth Pharmaceuticals SA/NV (formerly AHP Pharma SA/NV) and Aventis Pharmaceuticals Inc.). However, additional firms are increasing their efforts in the area either directly or in collaboration. For example, Baxter is joining efforts with the British company,

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Acambis plc, in providing the U.S. government with over 150 million doses of smallpox vaccine.

[0006] The price of vaccines, such as an influenza vaccine, has been rapidly increasing and is expected to continue to increase in the coming years. That change is due to various Food and Drug Administration (FDA) mandated improvements in manufacturing practice and formulation, which has led to single-dose packaging (i.e., from multi-dose presentation) and increase use of single-dose pre-filled syringes and other delivery systems. Furthermore, requirements for injection safety and needle-stick protection provide further justification for upward pressures on per dose pricing, and a more attractive environment for vaccine producers. Indeed, despite trends at consolidation elsewhere in this pharmaceutical segment, new players are entering this market (e.g., Baxter Healthcare Corporation, PowderJect Pharmaceuticals Plc) and could benefit from partnering with organization(s) offering the present invention described below.

[0007] The market for vaccine delivery tools (i.e., currently standard needles and syringes, safety-engineered syringes to prevent needle-stick injuries, pre-filled syringes and nasal spray devices, and jet injectors) is a highly concentrated market, with Becton, Dickinson and Company (BD) capturing over 70% of the market. The distribution of vaccines is also concentrated, and the top three distributors (i.e., McKesson Corporation, Cardinal Health Inc., and Bergen Brunswig Corp.) are capturing more than 85% of the market, and suffering from reduced margins as a result of pricing pressures.

[0008] A need exists for a system such as the present invention described below that can assist the participants in this layer by offering tools to assist them when incorporating information from the immunization process into their supply chain management system.

Fragmented Vaccine Administration (Providers and Points of Service)

[0009] The healthcare delivery industry in the United States is highly fragmented and lacks consistent quality of service. In particular, the immunization market has characteristics that lend itself to centralized information systems (such as centralized registry and recommendation systems) and immunization programs management systems (e.g., the service does not require on-site medical doctors, but rather standing orders issued by a physician medical director for qualified nurses providers). The healthcare delivery industry therefore remains highly inefficient in the manner in which it records and analyzes information, and in the way it ensures consistent and high quality immunization administration service.

[00010] Most immunizations are administered today at one of three types of locations, that is, physicians' offices, community clinics and medical center outpatient departments, which together are responsible for over 80% of the market. However, the vaccine

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administration market is highly fragmented, with no single administrative organization, or point of service network responsible for more than 5% of the market.

[00011] Immunization itself does not require medical doctors on the premises for supervision, and therefore is feasible in settings out of health clinics, that is, so called "non-traditional" settings. In recognition of the importance of such settings for accelerating immunization coverage, new guidelines have been issued by the Center for Disease Control (CDC) in 2001 to further enhance their use. Market research indicates that most people, particularly adults, will find locations such as drug stores or worksites to be more convenient for receiving immunization than health clinics. Part of the key to success of an organization offering a service such as the present invention described below is the ability to leverage this consumer inclination to facilitate offerings at national drug store chains (60,000 locations in the U.S.) and at work-sites, providing increased convenience to consumers, and enhanced compliance monitoring for employers.

[00012] On the provider side, nurse aggregation organizations, usually isolated, could join a certified providers network and benefit from being associated with a high quality brand and become eligible to service referrals to clients previously unobtainable. An organization managing a service such as the present invention described below could also allow for national plans to be coordinated for retail chains and multi-location employers, whereby different providers belonging to the network will provide the immunization service at different locations with a standardized quality, cost and information platform while reducing large risks and costs inherent in managing such an effort independently.

Immunization Information Systems

[00013] Information systems play a significant role in healthcare, but currently, they are not utilized in an efficient or useful manner in the immunization market. For example, there is currently no national registry system for the tracking of immunization of adults or children. However, in the last 7 years, more than \$250 million has been spent, by government and state agencies, on state pediatric registry systems. Many of these systems are now defunct due to state-based contracting with small software companies that went bankrupt. The present invention described below provides a platform that is superior to any available system by being designed to offer a national private sector registry as part of the benefits of utilizing its services. This registry will be available to children, adolescence and adults.

[00014] The CDC has an initiative (termed "Vaccine Identification Standards Initiative" or VISI) to provide machine-readable tracking information on vaccines. This initiative, although supported by the major vaccine companies, has not yet been implemented. Such tracking has begun in Europe and is required in some countries there, and this trend is expected to continue. Such vaccine identification system could be combined with input units

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such as barcode readers connected to a mobile unit of the present invention. This vaccine safety enhancement tool will provide another benefit for medical providers such as hospitals and clinics implementing the system because this component of vaccine administration is the largest nursing dissatisfaction in immunization programs. Moreover, vaccine manufacturers desire that such information be collected both as a method of improving vaccine supply chain efficiency and re-distribution, as a value-added feature to position higher value vaccine packaging and pricing, and as a desired epidemiological tool to more expeditiously conduct investigations of adverse events and avoid larger product recalls than needed.

Bio-Warfare Preparedness

[00015] In recent years, attention to national preparedness for bio-warfare scenarios has increased. However, resource allocation in that area had been limited, and was focused instead on disease surveillance by specialists, and not on development of an infrastructure for mass and rapid vaccine delivery capabilities at community levels for emergency situations such as smallpox, anthrax, or influenza pandemic disease occurrences.

[00016] Immunization against infectious diseases is a recognized and heavily funded, critical component of national bio-terrorism preparedness and armed forces defense. The market has naturally segmented itself into two distinct portions concerned with likely bio-agent threats, that is, (a) deployment of existing vaccines to military and civilian populations, and (b) the accelerated development of new vaccines to counter likely bio-terror agents. The most significant and immediate priority is immunological defense against smallpox. This infectious disease had been eradicated in 1978, following a global immunization campaign, but has reportedly been weaponized by the former Soviet Union and may also be available as a weapon of mass destruction in Iraq, Syria, Iran and North Yemen, among others. Indeed, as the anthrax exposures in October 2001 have clearly indicated, even a single re-introduction of this disease could create a national and international health crisis.

[00017] Various simulations and live-scenario analyses (including the widely reported "Dark Winter" exercise) have indicated that without full and rapid response, smallpox spread undetected and uncontrolled could rapidly result in millions of deaths and disruption of service across a nation. For these and other reasons, the United States government has recognized smallpox to be its primary bio-threat for which mass immunization could be deployed.

[00018] Intense public and high-level policy debate is beginning on which strategies will be used for smallpox vaccination preparedness. As of January 2002, the U.S. government has different immunization plans according to the specific needs of each group: (1) pre-event immunization for military and reserve forces; (2) pre-event immunization for family members of military and reserve forces (3) pre-event immunization for core first responders (4) pre-

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event immunization for all first responders (5) post event, rapid immunization (<3 days) for designated populations (6) post event, rapid (< 3 days) immunization for all populations. Regardless of the combinations and evolution of strategies, the system of the present invention described below can accommodate all these strategies using ongoing direct involvement at the public health policy levels.

Summary Of The Invention

[00019] In accordance with the present invention, an immunization data system comprises single or multiple networked mobile (e.g., portable) or stationary units, connected directly or via a local server to a centralized data-center. The system provides management and referral tools for point of care managers such as states, worksites, pharmacies and retail stores interested in solutions for immunization and bio-warfare preparedness services, information tools such as lifetime vaccination tracking, and a vaccination recommendation engine to address the needs of consumers and employers.

[00020] The immunization data system collects and stores immunization and disease data. The networked mobile (e.g., portable) or stationary units (hereinafter referred to as "immunization mobile stations" or IMSs) are provided with a software application to facilitate the collection of patient information such as biographical data, previous vaccination data, medical history, medications in use, occupation, administration of recent vaccination, disease symptoms and the like. IMSs synchronize the patient information with information stored in a database maintained at a data center that is accessible to different groups of personnel based on different privileges defined at the data center and other security measures. Patients can access electronic patient records created by the IMSs, and stored at the IMSs and/or a local server and eventually at the data center, via telephone or computer (e.g., via web browser). IMSs can capture and store images of vaccination and disease symptom sites on patients. The database allows for vaccination and disease tracking and disease control. The IMSs can be provided with electronic patient consent forms, and are programmable to track adverse events and create follow-up reports after a vaccine is administered.

[00021] In accordance with an embodiment of the present invention, a method of collecting and storing immunization data for a patient is provided that comprises the steps of: (1) running an application on a computer at a vaccination site for entering patient information selected from the group consisting of name, age, gender, address, medical history, medications in use by the patient, occupation, and previous vaccination data; (2) storing the patient information as an electronic patient record; (3) generating information relating to a vaccination for review by the patient; (4) obtaining patient consent to receive the vaccination

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by generating an electronic consent agreement and storing the patient's digital signature acknowledging acceptance; and (5) entering new vaccination data relating to the vaccination into the electronic patient record when the vaccination is administered to the patient.

[00022] In accordance with another aspect of the present invention, the method further comprises the steps of generating a digital image of a vaccination site on the patient, and storing the digital image in the electronic patient record. In addition, disease information comprising symptoms (e.g., for smallpox) experienced by the patient can be entered and stored in the electronic patient record. The IMSs are configured to generate a digital image of a smallpox lesion site on a patient, and store the digital image in the electronic patient record.

[00023] In accordance with yet another aspect of the present invention, the disease information in the database is accessible by personnel selected from the groups consisting of a disease control center, a state government office, a federal government office, a medical center. Also, a patient can access the electronic patient record using at least one of a web browser and a telephone transaction.

[00024] The system of the present invention is configured to collect and store adverse effects information comprising symptoms experienced by any of the plurality of patients following their vaccination in the corresponding the electronic patient record.

Brief Description Of The Drawings

[00025] The various aspects, advantages and novel features of the present invention will be more readily comprehended from the following detailed description when read in conjunction with the appended drawings, in which:

[00026] FIGURE 1 is a system block diagram illustrating a business process according to an exemplary embodiment of the present invention;

[00027] FIGURE 2 is a system block diagram of an immunization data system constructed according to an exemplary embodiment of the present invention;

[00028] FIGURE 3 is a block diagram of an exemplary immunization mobile station constructed in accordance with an embodiment of the present invention;

[00029] FIGURE 4 is a block diagram of an exemplary data center constructed in accordance with an embodiment of the present invention;

[00030] FIGURE 5 is a block diagram illustrating different configurations for connecting an exemplary immunization station to a data center in accordance with an embodiment of the present invention;

[00031] FIGURE 6 illustrates an immunization data system constructed in accordance with the present invention comprising an immunization station, a local server and a data center; and

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[00032] FIGURES 7 through 29 are exemplary screens generated by an immunization mobile station or at a data center in accordance with an embodiment of the present invention.

[00033] Throughout the drawing figures, the reference numerals will be understood to refer to like parts and components.

Detailed Description of the Preferred Embodiments

[00034] FIGURE 1 is a block diagram illustrating a business process employed by an immunization data system 10, according to the present invention. Transactions within the immunization data system 10 can involve service providers 12, patients 20, customers or points of service (POSSs) 30, a service management company 44 and payors 46 for services. The service providers 12 can include, but are not limited to, personnel that administer vaccinations such as public health (PH) nurses 14 and private sector nurses 16, as well as nurse or other health professional aggregators 18. The patients that receive vaccines, have adverse reactions to vaccines, exhibit disease symptoms, or otherwise desire access to a database of disease and immunization data can include, but are not limited to, soldiers and their families 22, employees 24, first responders 26 to an emergency such as a bio-terrorism attack, and civilians 28. Customers and POSSs that need access to, as well as collect the data for, the database of disease and immunization data can include, but are not limited to, national government facilities 32, retailers (e.g., drug stores) 34, corporate health care administrators 36, state health program facilities and administrators 38, health clinics and offices 40 and hospitals 42. A service management company 44 is preferably any entity that provides an interface between any of service providers 12, patients 20, customers or points of service (POSSs) 30, and payors 46 for services. The payors 46 can include, but are not limited to, insurance companies 48 and the patient 50.

[00035] As described below in connection with FIGURE 2, the system 10 is preferably a combination of computer hardware and software tools designed to enable an immunization program to be conducted in multiple environments. For example, for emergency bio-terror activities, the system 10 allows for a state or other government entity to license a system and incorporate it into its preparedness plan to have a paperless process in place for tasks such as immunization administration, case finding and adverse events follow-ups. The providers 12 of the services in this case will typically be public health (PH) nurses 14 and private sector nurses 16.

[00036] Another illustration of the applicability of the system 10 is for routine immunizations at worksites. The manager of the system 10 provides a matching service between the immunization providers using the standardized system and the corporations desiring the service.

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[00037] Utilizing the system 10 offers various participants in the immunization market significant benefits. For example, benefits to consumers or patients 20 and providers 12 can include, but are not limited to: (1) providing consumers with objective information, support and updates regarding immunization; (2) providing personalized health information while adhering to the strictest confidentiality standards, with the advantage of personal health information handled by the private sector, as opposed to state or government agencies (as it is the case with the pediatric registries); and (3) providing valuable, credentialing for nurses.

[00038] Benefits to customers and points of service 30 can include, but are not limited to: (1) a tracking system that allows for updated information, and for annual reminders, supporting achievement of high immunization coverage for high risk and other targeted patient groups at low cost (e.g., such coverage is often viewed as an important indicator of service quality by third party payors, consumers and other agencies); (2) a tracking system that provides an effective tool for loyalty enhancement; (3) allowing pharmacies, retailers, worksites and governments to benefit from a standardized technology platforms and work processes for the management of immunization programs; (4) and a tracking system that offers a simple tool to provide otherwise burdensome information to patients, and provides a simple, low cost employer solution to monitor compliance with regulatory requirements.

[00039] Benefits to health programs 38, in particular, state health programs can include, but are not limited to: (1) significant cost saving and rapid implementation through a standardized, modular approach; (2) highly scalable design leveraging existing technologies to expedite development and reduce costs; and (3) meeting emergency preparedness needs while strengthening routine disease control and immunization programs.

[00040] FIGURE 2 illustrates the block diagram of the immunization data system 10 according to an embodiment of the present invention. The system 10 preferably comprises at least one data center 82 for storing immunization data collected by one or more immunization mobile stations (IMSs) 80, among other data. As will be described below in connection with FIGURE 3, the IMSs 30 are generally located remotely with respect to the data center 82. The data center 82 is accessible by vaccine suppliers' computer systems, as well as by patients and providers, indicated generally at 86, directly or indirectly via a call center 88. Registries and surveillance tools 94 can access and use the data center 82 directly or indirectly via, for example, servers 92 maintained by states, and government agencies such as the Department of Defense (DOD) and Center for Disease Control.

[00041] The immunization data system 10 can be implemented by hardware and software components specifically designated to implement the present invention, or by using hardware and software components and other infrastructure that already exists. As an example, an immunization mobile station (IMS) 80 can be connected to the data center 82 via Internet

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connections, closed circuit connections, or direct lines. The computer system for the IMS can be specially designed computers, or existing computers and technologies such as the preferred embodiment utilizing mobile computers such as a Tablet or Pocket personal computer (PC).

[00042] With reference to FIGURE 3, the IMS 80, which is primarily used for data entry, comprises a central processing unit (CPU) 100 for performing processing functions, a Read Only Memory (ROM) 102 and a Random Access Memory (RAM) 104. The ROM 102 stores at least some of the program instructions that are to be executed by the CPU 100, and the RAM 104 provides for temporary storage of patent, immunization and disease data. The term CPU, as generally used herein, refers to any logic processing unit, such as one or more microprocessors, application-specific integrated circuits (ASIC), and the like. While the CPU is described separated from other components such as the ROM, some or all of these components may be monolithically integrated onto a single chip.

[00043] A communication port or other interface 106 in the IMS 80 facilitates communication between the CPU 100 and devices external to the IMS. Information between CPU and remote locations such as the data center 82 and a seller computer system can be sent via modem, for example. The illustrative embodiment described herein employs a modem and a wireline link to communicate with devices outside the buyer/seller computer system; however, other paths and methods of communicating with external devices can be used without departing from the spirit of the invention, including, but not limited to, wireless communications and optical communications.

[00044] The IMS 80 computer system also includes one or more input/output (I/O) devices such as a display 110 and a data entry device 108 for use by the patient and the medical provider, for example. A wide variety of I/O devices can be implemented for this task, including, but not limited to, a touch screen, a keyboard and a mouse. The I/O device 108 may be linked to the CPU directly or via an intermediate or wireless connection such as an infrared link. In accordance with an aspect of the present invention described in more detail below, the IMS 80 is preferably configured to receive and store images obtained, for example, via a digital camera 112. The IMS 80 is therefore configured to collect and store patient data such as images of a patient's smallpox lesions for better disease monitoring, study and control.

[00045] The information entered via the IMS 80 is transmitted to the data center 82 for storage and analysis, or is stored and analyzed by a software program located on a local computer system described below in connection with FIGURE 5. The immunization data system 10 of the present invention supports all of the relevant tasks associated with providing high quality immunization delivery service. Among other tasks, the system 10 provides information on dosing schedules for vaccines, supports point of service data entry, provides

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manufacturers with complete lot tracking, provides consumers with immunization lifetime tracking, contains an immunization recommendation engine based on previous vaccination, demographic, travel, health risk, occupational status and other voluntary information inputs, and provides up-to-date, accurate, on-demand information about vaccines, based on information from an independent panel of expert clinicians.

Main Data Center

[00046] With reference to FIGURE 4, the main data center 82 preferably resides on a main server 116 and employs an administrator application 118 to configure the IMSs 80 or other software used at the points of service 30. Access rights, database analysis tools, and the rules, procedures and methodologies are preferably defined for all users at the main data center 82. Similarly, the definition of point of service level security privilege is conducted at the data center 82. An interfacing engine 120 allows the import and export of data from and to other information systems, including surveillance systems, state registries, billing companies, and data systems of the points of service.

[00047] At the data center 82, a vaccine preventable disease database 122 preferably resides to provide caregivers and consumers with information related to vaccine preventable infectious diseases and the ability to check sequence vaccine administration. The database 122 also allows access to data on risk-based exemptions to prevent adverse events and provides context-based vaccine recommendations (e.g., vaccination recommendation for business travel and personal health promotion).

Immunization Mobile Station (IMS)

[00048] The IMS 80 is a combination of applications residing on mobile units such as a standard Tablet PC or a Pocket PC. In the case of a Tablet PC, peer-to-peer data sharing is available across units in a pre-defined proximity, even when a wide area network (WAN) is not available, providing the ability to conduct multi-unit immunization in the field without internet or LAN connectivity. The IMSs 80 are essential tools in providing the ability to have a paperless immunization process anywhere, anytime using traditional and non-traditional channels (e.g., schools and worksites). In addition, the IMSs 80 are configured so that some information is always being retained on the unit in the event the Internet or other connection is lost for a period of time.

[00049] The IMSs 80 are used for interfacing with patients at the points of service 30, and include immunization administration tools. The applications available on each IMS 80 include, but are not limited to:

- Intake patient information: (e.g. name, address, age);
- Previous available immunization information, if not otherwise in the system;

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- Recommendation engine with suggested vaccinations due and next recommended visit date;
- Vaccine Information Statements (VIS); and
- Informed Consent with electronic signature capability; FAQs to answer questions about the vaccine schedule, contraindications and/ or recommendations.

[00050] For the case of a bio-terror immunization program, specialized modules can be incorporated into the IMS 80 with the following core and optional enhanced features, for example:

- Investigational New Drug consent, monitoring and tracking forms to allow for automated compliance with CDC and NIH extensive mandated protocols for adverse events and side effects documentation; and
- Global positioning/mapping software to allow for simplified case investigation, contact tracing and analysis of both epidemic spread and control efforts with web-based real-time analysis (for ring containment, this essential tool facilitates coordinated quarantine, tracing and immunization to highest risk individuals in the field or at fixed site immunization stations).

[00051] The IMS 80 preferably provides a health management tool that gives patients the ability to build a permanent electronic immunization record in which health information can be collected at the IMS 80 and securely stored (e.g., at the data center 82) as it accrues over time. The data center 82 is accessible by patients and providers with access-rights via computer or telephone. Security for input and retrieval of data allows records to be accessed, with patient permission, to satisfy various periodic vaccine documentation needs from schools, camps, tours, employers and others who require such information. For example, for smallpox immunization, the record could include follow-up tracking information and adverse events follow-up information, including digital images of the lesions requiring expert assessment and notification to state authorities.

[00052] The immunization data system 10 can be implemented in many different settings. For example, by way of illustration, three methods of connecting the IMSs 80 to the data center 82 are described. There are several ways in which the IMS 80 can connect to remote networks (e.g., in the field with other IMSs 80) or to the main network 82 (e.g., in a clinic, etc). The IMS can be installed on a standard mobile computer, such as a Tablet PC. Through built-in wireless support (e.g., wireless network cards), Tablet PC's can communicate directly with one another in the field by forming "ad-hoc" networks and exchanging information over their wireless cards. In each group of Tablets PCs, one of the units is designated the group master and retains all updated information regarding the group. In environments where the main network is accessible, the Tablet PCs 80 can be connected to the data center 82 by using

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their wireless connection to communicate with a wireless access point (WAP), or by utilizing a docking station which is already connected to the main network that connects the IMSs 80 to the data center 82. However, in order to retain the ability to work without internet connectivity, group master units 80 preferably retain all updated group information. All wireless communications between Tablet PC devices 80 and/or WAP devices can be encrypted to ensure secure data transmission. As an alternative to the peer-to-peer communication described above, another notebook computer can operate as a local server.

[00053] FIGURE 5 illustrates different possible working modes. The IMSs 80 (e.g., Tablet PCs) indicated at 130 represent units working in stand-alone mode, capturing all of the data on the unit 80. The IMSs 134 can also have connection to the data center 82 and synchronize the information with it once they have connectivity, as indicated at 132.

[00054] The IMSs 80 indicated at 134 are operating in a Group Mode, where one Tablet PC (e.g., or a regular PC) operates as a group master for a group of IMSs 80 at, for example, a clinic or other site with multiple stations. Information regarding patients belonging to the group is preferably always maintained at the group master, even when there is an Internet connection to the data center 82, as indicated at 136.

[00055] During the period when there is connectivity with the data center 82 and the system 10 is operating in the Global Mode, the data is periodically synchronized to maintain consistency between the data center 82 and the group master. In order to switch back to a group mode or global mode, the data stored locally is transferred and synchronized to the master unit, or to the data center 82, correspondingly.

[00056] FIGURE 6 provides an overview of a system whereby an IMS 80 is part of a networked immunization process solution. While the description corresponds to a smallpox immunization process, the methodology can be easily applied to other types of immunization.

[00057] The methodology uses a data center 82 where preferably the entire database is retained and backed-up on multiple servers. The data center 82 is preferably connected via the Internet to mobile clinics. Data from local mobile servers 140 are replicated to the data center when an internet connection is available and connection to the data center is initiated. Each mobile clinic is (e.g., IMS 80) based on a local mobile server 140 (e.g., a notebook computer) where the clinic data is replicated, a wireless access point and a printer, as well as a number of IMSs 80. Each IMS 80 (e.g., a Tablet PC and a digital camera) is designed to communicate with the local server 140 using a wireless connection, and directly with the data center 82. The digital cameras can be used to document the patient and skin lesions and, subject to state policies and privacy compliance programs, the resulting patient data set can be designed to be accessible remotely by state designated officials. State designated officials can have access to the entire information residing at the data center 82.

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[00058] Forms and procedures are provided by each IMS 80 to add a new patient record or to pull an existing patient record. Each IMS 80 can also a personal information page, an informed consent form (with digital signature), a medical history questionnaire (including current medications), a summary page, a smallpox immunization record screen, follow up (diary card) screens, an adverse events screen, among other forms and screens. The screens can be filled via the IMSs 80, which are based on configured Tablet PCs, which allow for signing on the screen. The IMS 80 also allows for the printing of various forms, such as the patient card (which describes details such as the date of vaccination), and the CDC Vaccine Adverse Event Report (VAERS). Summary information regarding the number of patients that visited the clinic can be obtained from the data center, via the internet, using standard browsers, such as Microsoft Internet Explorer. The IMS application environments will now be described.

Exemplary Clinic/Pod Equipment Layout

[00059] Each clinic preferably comprises a stationary master tablet PC or another notebook computer 80 and a few other Tablet PCs 80 that are most likely portable devices. The master PC acts as a local database server and as an additional unit in the clinic to run reports and access patients' files. For example, if the clinic manager needs to run a report, he will be able to do this using the master PC without interfering in the operations of other staff members or their respective IMSs 80. Having one extra Tablet PC in each clinic that is stationary ensures reliability of the application at a low cost and prevents malfunctions that can occur if it were a portable unit.

Data Services Tier

[00060] Each local IMS 80 could use a standard database client such as Microsoft SQL Server 2000 Desktop Edition (MSDE), a low cost database engine which provides SQL Server compatibility. The data center 82 preferably uses a standard database such as a Microsoft SQL Server 2000.

Security

Application

[00061] Access to the IMS 80 application is preferably controlled through a username and password login. Administration of the accounts are preferably handled by senior Help Desk personnel.

Network

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[00062] With continued reference to FIGURE 6, network communication between Tablet PCs 80 and wireless access points indicated generally at 140 in each clinic or other site can be secured using standard security measures, such as 128-bit wired equivalent privacy (WEP) encryption protocol. In addition, other security measures can be used such as data packages transmitted between Tablet PCs 80 and access points 140, or other Tablet PCs can be encrypted using IPSec protocol. Network communication to the data center 82 servers 82 are preferably over the Internet using HTTPS protocol.

Physical

[00063] Placing the central database servers in a hosted data center environment 82 provides the best physical security. Access to the servers is preferably controlled by key card access and sign in via security personnel. Hosting providers can also provide network security through use of firewalls, monitoring, and encryption technologies.

Database Security

[00064] The database resides behind a firewall that enables access only to authorized users.

Application Layout

General Rules

[00065] The application at each IMS 80 preferably follows a set of rules such as the exemplary rules described below that are preferably applicable throughout the entire application screens and forms.

System Login

[00066] Each user has a username and password, and has to provide this information in order to access the application.

Patient File Audit Trail

[00067] The application creates a log item when a patient's records are created or updated. In each area of the application, the user has the ability to view the patient's log. The system preferably automatically records (without involving the user) the following information:

- Patient name
- Date
- Time

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- User Name
- General activity described in terms of application area used

Date Fields

[00068] Date fields are text box fields with a date icon next to them. The user can either fill in the field by typing the date or by clicking a date icon that opens a calendar and allows him/her to go back and forward in increments of months and years. Clicking on a specific date in the calendar closes the calendar and displays the selected date in the date text box.

Numeric values

[00069] In numeric fields, the IMS application allows only numeric values. No alphabetic values are allowed in these fields. In addition, for each field, there is a valid range that are defined in the system tables. If the value entered is above or below this range, the system displays an error message. For example, the system does not allow entry of a value such as 150 in the temperature field.

Grids

[00070] Each table in the system that displays information can be sorted. The sorting fields are the table headers. The sorting is done by double clicking on the header field the user wishes to sort by. The first time the user double clicks on the grid, the IMS application sorts the data in ascending order. The second time the user double clicks the grid header, the IMS application sorts the data in descending order. The application can sort both numeric and alphabetic values.

[00071] The decision to use a grid or not to display a list of questions is a user interface decision that is made on a case-by-case basis to ensure the best accessibility and usability for each portion of the application.

[00072] As a general rule, and unless otherwise specified, a tab with five additional positions for questions is preferably provided in each of the sections containing questions. These questions are not required or predetermined by the application. The user enters both the question and the answer. The questions are labeled plainly (e.g., Q1-5). Each question has three available fields labeled:

- Question- Text box
- Yes/ No - Checkbox
- Details - Textbox

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Application Container Window

[00073] The IMS 80 application is preferably a Windows application. A screen can comprise one or more of a top frame, an action form and a bottom status bar, as described below.

Top Frame Menu Items

[00074] The top frame contains high-level menu items. Clicking on any of the following menu items opens a new window inside the application. The items are divided into logical areas that support the vaccination process in the clinic or at the field. The availability of items in the top frame menu depends on the status of the vaccination process of the individual patient. For example, the user will not be able to click on the Enrollment item before completing the Consent form. The rules for the menu items will now be discussed.

Search/Open

[00075] Clicking the Search/Open menu item 156 displays the search form (FIGURE 8) that allows the user to search for existing users in the immunization data system 10.

New Patient

[00076] Clicking the New Patient menu item 158 displays a new patient form that allows the user of the IMS 80 to enter new patient information.

Consent

[00077] Clicking a Consent menu item (not shown) or completing a new patient form, displays a Consent form that allows the patient to read and sign on a consent form.

Enrollment and Vaccination

[00078] Clicking an Enrollment or Patient Information menu item 160 displays an enrollment form that allows the user of an IMS 80 to enter medical information about the patient and his family, record vaccination information, take pictures and have the patient sign after the vaccination process.

Follow Up

[00079] With continued reference to the exemplary application screen in FIGURE 7, Follow Up menu item 162 displays a follow-up form that allows the user to enter follow-up information about a patient, including medical information regarding the vaccination given, record additional pictures, and enter details about physical exams given.

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Adverse Events

[00080] Clicking an Adverse Events Menu item 164 displays an Adverse Events form that allows the user to enter adverse events information that happened to the patient.

Administration

[00081] Clicking an Administration Menu item (not shown) displays an administration tab that allows the user to define and change a list of items.

Reports/Queries

[00082] Clicking on the Reports/Queries Menu item 166 displays a list of reports that can be printed for the selected patient and a list of available queries.

Action Form

[00083] This is the sub-window within the application that will open after the user clicks on any of the Top Level menu items. The action sub-window contains input and output displays. Depending on the menu item option the user selected, the look and feel of the action form (e.g., FIGURES 8 through 29) can be slightly different. In general, the action form has a few tabs. Each tab has its own title and enables the user to complete a data entry section in a logical way.

[00084] The action form follows, in most cases, the following rules:

- has a save button
- has a cancel button
- has a view patient log button
- If there are multiple tabs, arrow buttons on the bottom of the form are provided to allow the user to move between the tabs in a logical order.
- The form title will read the name of the menu item the user clicked on.
- The top most part of the form reads again the name of the menu item the user clicked on and appends a dash and the patient name.
- There is only one action form subwindow open at a time; preferably fills the available space in the application window under the top level menu items.

Bottom Status Bar

[00085] The status bar is preferably an indication for the following items:

- Patient Information (e.g., First Name, Middle Initials and Last Name)
- System Mode (e.g. Stand Alone, Group or Full Network Mode)
- Application Version.

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Users Actions

[00086] This section describes the action available for the users, and the order in which the system allows the actions to occur.

Search/Open

[00087] This is one of two options available to the user in the top frame menu items upon launching the application. Clicking on the "Search/Open" menu item brings up a search form (FIGURE 8). The search form allows the IMS 80 user to search for existing patients in the system. The user is able to search for existing patients using the following criteria fields:

- First Name
- Middle Initials
- Last Name
- Vaccination Date
- Immunization system internal identifier
- Biometric Information (if entered)
- Social Security Number (if entered)

[00088] As shown in FIGURE 8, when the user clicks on the Search button 170 and the IMS 80 is connected to the data center 82, the system 10 searches in the database 122 at the data center 82 for matching patients. The system 10 can find 0 to n matching patients and displays them in the result grid. The information displayed in the result grid is:

- First Name
- Middle initials
- Last Name
- Vaccination Date
- Immunization system internal identifier
- Social Security Number (Optional)

[00089] In all of the alphabetic fields, the IMS 80 application, by default, appends an asterisk to the end of the field. For example, if the user types 'a' in the first name field, the application retrieves all the patients whose first name begins with an 'a'. The asterisk field is not displayed on the form.

[00090] The application limits the number of results to a pre-defined value (configured by authorized personnel), with the default being 200. If more than 200 patients answer the search criteria, the application will notify the user and advise to add more search criteria.

[00091] The user can then either double-click on a row in the result grid or select a row and click on the Select Patient button. The system 10 then closes the form and changes the status bar to display the selected patient information.

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[00092] If the system 10 cannot match any patient to the search criteria, it displays a Yes/No message box saying "No Patient Found – Create new patient?" If the user chooses "No", he is returned to the search form that remains pre-populated from the previous search. If the user chooses "Yes", the IMS application closes the Search/Open form and takes the user to the New Patient form, which is preferably pre-populated with the information the user searched for (excluding the vaccination date).

[00093] The application does not allow for a search if all of the search criteria fields are empty, and displays an error message if this is the case. In addition to the Search and Open buttons, the IMS generates a screen with a Clear button that will clear all of the fields from the form if detected.

[00094] If a biometric device is connected to the Tablet PC, the application displays an additional button that allows the user to search for a patient using his/her fingerprint.

New Patient

[00095] Choosing the New Patient menu item 158 changes the application status bar 154 to read "New Patient". It closes the current open patient record (if a patient record was open). A New Patient form (FIGURE 9) opens and allows the user to enter the patient information. The available fields are (mandatory fields are specified), but are not limited to:

- First Name – Textbox - Mandatory
- Middle Initials – Textbox
- Last Name – Textbox - Mandatory
- Social Security Number (Optional)– Textbox
- Date of Birth – Textbox
- Gender (radio button) - Mandatory
- Ethnicity (combo box)
- Home Phone – Textbox
- Work Phone – Textbox
- Cell Phone- Textbox
- Fax Number –Textbox
- Email - Textbox
- Home Address – Textbox
- City – Textbox
- State (combo box)
- Zip Code – Textbox

[00096] The Ethnicity and State fields are pre-populated with values. The default value for the state is predefined in the database 82 or local database 80 or 140. The form also has

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Save, Cancel and Save & Print buttons. When clicking on the Save button, the application checks if all the mandatory fields have values. If one or more fields are missing, the system displays an error message and returns to the form; otherwise, it closes the form. The Save & Print button performs the same tests as the save button but also causes printing of a patient card. The user can also click on the Cancel button, in which case the form closes and the status bar reads "No Patient"

[00097] The IMS application might have an optional biometric device that enables a user to record the patient fingerprint. If such a device is enabled, the application allows the user to record the patient's fingerprint. The fingerprint is stored in the database 80 or 140 and eventually the data center 82, and is used as another field to search for the patient records.

Consent

[00098] After opening a current patient record or creating a new patient record, the IMS 80 application allows the user to click on the Consent menu item to open a new action form displaying a consent form (e.g., FIGURES 10 and 11) that has a place for four signatures:

- Patient's signature
- Signature of person conducting informed consent discussion
- Signature of investigator or approved designee
- Witness to consent procedure (optional signature)

[00099] Next to each of the signature boxes, the following buttons are available:

- Sign – to enable the signature box
- Save – to save the signature
- Clear – to clear the current signature

[000100] If no signature is stored in the database 80 or 140 and eventually 82, the patient signs in the designated signature box. The patient can sign on the screen of the Tablet PC 80. The digital signature is then stored in the database as an image. At the bottom of the consent screen are Print and Cancel buttons. The Print button initiates printing of the consent form when selected, including the signatures at the appropriate positions. The Cancel button closes the form. The system 10 does not allow for any other menu item to be available until the patient signed on the consent form.

Enrollment and Vaccination

[000101] After signing the consent form, the IMS 80 application enables the Enrollment menu item. By clicking the Enrollment menu item, the user obtains a new action form that has multiple tabs. Each tab represents a different part in the vaccination process. In addition, the Enrollment action form allows taking pictures of the vaccinated area of the patient and storing the pictures in the database 80 or 140 and eventually 82, as well as

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uploading of external files. The user can save his work at any stage by clicking the Save button. The Cancel button closes the form. The next few sections describe the tabs available on the enrollment form.

Medical History

[000102] Selecting the Medical history tab displays general questions about the patient medical history. Each question can be answered both for the patient and for a household. The questions are displayed in a grid. Each row in the grid has four cells:

- The question
- Patient cell – each cell with 2 checkboxes, Yes and No
- Household cell – each cell with 2 checkboxes, Yes and No
- Additional information – a form-free text area where the user can type.

[000103] Some of the questions might require the user to enter additional form-free text in a designated area. In these questions, the IMS application indicates to the user what type of information needs to be provided.

[000104] The following table contains exemplary questions:

Question	Remarks
Heart disease	
Stroke	
Seizure	
Asthma/emphysema	
Cancer /leukemia	If Yes, need to specify what type, when it was diagnosed and how it was treated.
Eczema	If Yes, the user has to enter in the free text box if it's active or "history of" and for what period of time
Other chronic skin condition	If Yes, needs to specify what type, when it was diagnosed and how it was treated.
Acquired Immune deficiency (HIV)	
Autoimmune disorder (ex: lupus)	If Yes, needs to specify what type, when it was diagnosed and how it was treated.
Hepatitis	
Frequent/recurrent/severe infections	If Yes, needs to specify what type, when it was diagnosed and how it was treated.
Other	If Yes, needs to describe

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[000105] Additional questions might be added to this grid.

Current Medications

[000106] After selecting in the current medication tab (FIGURE 12), the user is provided with a screen (FIGURE 13) to enter information about any medication currently being taken. In order to enter information in the grid, the user will first have to check a "Yes" checkbox in response to query "Is the patient currently taking any medications (prescription and/or over the counter)". The form has a grid with 4 columns:

- Medication name
- Medication dosage
- Start Date
- Reason for taking

[000107] The screen in FIGURE 13 has text boxes with the above titles as the grid columns in which a user enters the information. The lines are displayed in the order they were entered. The user is able to click on a line and choose to delete it. The entry fields for medication names and dosage fields are pre-populated lists. The pre-populated lists include the value "Other". If the user selects "Other", the user can enter data in an associated text box.

Vaccination History

[000108] Selecting the vaccination history tab (FIGURE 12) causes the IMS 80 application to generate an Immunization History screen (FIGURE 14) that preferably consists of three parts:

Previous vaccination for smallpox

[000109] This is a Yes/No question. If the user chooses the "Yes" checkbox, a textbox for entering additional information such as when/where is be enabled. The text box allows for entry of the following information:

- Vaccination date (if known)– text box
- What was your age range? –pull-down menu (0-5; 6-10; 11-15; 16-20; 21-30; 31-40; 41-50; 51-55; 56-60; 61-65; 66-)
- Was it in childhood? –Y/N
- Was it in military service? – Y/N
- Lot number (if known)– text box
- Location – combo box

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- Number of doses – text box
- Was the information based on recall or document?- R/D
- Remarks – text box
- Take Response- check one of the following: Normal; No Take; Scar; Adverse Event; Equivocal)

Vaccinations received in the last 30 days

[000110] The screen in FIGURE 14 also has a Yes/No questions reading “Other vaccinations in the past 30 days?.” If the user checks the “Yes” box, a grid is enabled which has the following columns:

- Vaccination date – text box
- Vaccination type– combo box
- Lot number – text box
- Location – combo box
- Number of doses – text box
- Remarks – text box

Serious reaction to vaccination in the past

[000111] The screen in FIGURE 14 also has a checkbox question reading “Have you ever had a serious reaction after any vaccination?.” If the user checks the “Yes” option, a grid is enabled that allows the user to enter the following information:

- Description – text box
- Age – text box
- Vaccination - combo box
- Reaction after dose number - text box

Women Only

[000112] The women only tab can be enabled if the patient is a woman. The first portion of the tab preferably shows the following question: “Date of last menstrual period?” Below, there is a grid with a set of yes/no questions and a cell for remarks. The following questions are exemplary:

Question	Remarks
Are you currently pregnant?	
Are you currently Breastfeeding?	
Currently using birth control?	If yes the user will need to provide the name in the remarks area.

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[000113] Additional questions might be added to this grid.

Approval

[000114] Selecting the Approval tab causes the IMS 80 application to generate a screen such as the one in FIGURE 15 that displays all of the information defined in the application as essential for the physician to give the vaccination. This screen aggregates this information into one form and allows a physician to review it before proceeding with the vaccination process. The information displayed in this tab can be configurable.

Immunization

[000115] The Approval screen (FIGURE 15) can provide a signature box for obtaining a digital signature for storage. Alternatively, a separate Immunization screen (not shown) can be provided to allow the user to enter the following information

- Date of vaccination – text box
- Vaccination lot number – text box
- Vaccination site – combo box
- Vaccinator name – text box
- Signature box – digital signature box
- Sign button

[000116] The vaccinator name field will be pre-populated with the name of the user who is signed in to the Tablet PC, but the user can override it.

Photos

[000117] If the Photos tab in the screen depicted in FIGURE 12 is selected, a screen as shown in FIGURE 16 is provided to allow the user to capture photos of the patient vaccinated area. The screen preferably consists of two areas:

Photo Capture

[000118] This area allows the user to capture a photo using a digital camera attached (or connected via Wi-Fi) to the IMS 80 or load a photo from a file. Once the pictures are captured, the user can add a description to the photo and to click on the "Accept Photo" button to add the captured picture to the Stored Photos. If he chooses not to save the photo, the user can click again on the "Capture Photo" button to capture a new photo.

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Stored Photos

[000119] This area displays the captured photo(s) for the patient and the description. The user can double click on a picture to open in a new window. The user will then be able to zoom in/out from the picture.

[000120] A field is provided that the clinician, who is monitoring the picture taking, can use to fill in his/her name. The name field is pre-populated with the username logged in to the Tablet PC, but can be overridden by the user. Other screens can be generated by the IMS 80 application to allow a user to enter information regarding patient discharge, take response, and comments, as shown in FIGURES 17, 18 and 19, respectively.

Follow Up

[000121] After the enrollment process is completed, the IMS 80 application can enable the Follow-Up menu item (FIGURE 7). The form, as shown in FIGURE 20, enables the user to enter follow-up information up to 28 days. The user will have at the top of the action form a series of numbers from 1 to 28, each number representing a day. The user can click on one of the days and enter the information regarding the selected day. Clicking a day changes the title of the form to read the selected day, in addition to the other information. The form has Save and Cancel buttons. The forms can be filled by a clinician (e.g., in case of an Office visit, or a phone call to or from the patient). The patient can also complete the form over the internet using a web browser.

Diary

[000122] By selecting this tab, the IMS 80 application generates a screen as shown in FIGURE 21 that allows the user to specify if any symptom has occurred for that specific day. The screen has a grid with 3 columns in it as follows:

- Symptom/Question
- Yes/ No check box (or a numeric value)
- Additional information – a free text area where the user can type.

[000123] Some of the questions require the user to enter additional form-free text in a designated area. For these questions, the application indicates to the user what type of information he needs to supply. Also, a free-text area can be provided on another screen, as shown in FIGURE 22.

[000124] The form can have a Print Username & Password button that prints a unique username and password for the patient. There can be a web form on the internet that allows patients to fill the diary form from any standard web-browser.

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[000125] The following table contains an exemplary the list of symptoms/questions displayed in the grid.

Symptom/Question	Remarks
Scab fell off today?	
No Symptoms	
Temperature	
Fever	
Chills	
Joint pain	
Muscle pain	
Fatigue	
Loss of Appetite	
Cough	
Swelling/tender lymph nodes	
Itching on body	
Headache	
Backache	
Symptoms at Lesion Site:	
Pimple	
Vesicle (blister)	
Ulcer	
Scab	
Redness	
Swelling	
Warmth	
Itching	
Pain	If value exceeds 0, a description will be required.
Key: 0 = no pain 1 = painful to touch 2 = pain when arm is moved 3 = pain all the time	
Streaks on arm	
Vaccinia-type lesion NOT at site of vaccination	In case the user selects this symptom, the application will indicate a description and location are required in the additional information cell.
Non-Vaccinia type rashes	In case the user selects this

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	symptom, the application will indicate a description and location are required in the additional information cell.
Any new prescription medication taken?	If Yes, a description will be required.
Was Medical care sought today?	If yes, the following questions will appear: <ul style="list-style-type: none"> • Provider's Last Name • Provider's First Name • Provider's Address • Provider's Phone • Permission to acquire medical records – Y/N

[000126] If medical care was sought, and a permission to acquire the medical records was given by the patient, a signature box will appear on the screen to request the patient's signature. If the diary (i.e., FIGURE 21) was filled without the patient being in the presence of a user and his/her Tablet PC 80, (e.g., by using the web application), a message indicates a diary card needs to be signed and sent to the clinic in order to acquire the medical records.

[000127] Additional questions might be added to the grid depicted in FIGURE 21. For example, data ranges can be defined for each of the numeric questions so that the user can be alerted of abnormalities (e.g., a temperature above the average for patients on day 3). The text for the alert can be defined by a user with administrative rights. The alert could, for example, indicate that a referral to a clinician is recommended.

Photos

[000128] If the Photos tab on the Follow-Up screen (e.g., FIGURE 20) is selected, a screen such as that depicted in FIGURE 23 is provided to the user to allow capture of photos of the patient's skin, in each one of the diary dates. The screen can consist of two areas:

Photo Capture

[000129] This area allows to the user capture a photo using a digital camera attached to the IMS 80, or to load a photo from a file. Once the picture is captured, the user can add a description to the photo and click on an "Add

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"Photo" button to add the captured picture to the Stored Photos at the IMS or local server 140 and eventually at the data center 82. If the user chooses not to save the photo, he can click again on the "Capture Photo" button to capture a new photo.

Stored Photos

[000130] This area displays the captured photo for the patient and its description. The user can double click on a picture and open in a new window to zoom in/out from the picture.

Physical Exam

[000131] With continued reference to FIGURE 20, the Physical Exam form allows the user to enter information regarding a physical exam conducted with the patient. The examiner can select his/her name from a pre-populated list, and sign the form once completed.

[000132] The user can enter the following exemplary information:

Symptom/Question	Remarks
Inner bump/vesicle (mm)	
Narrow ring of bright red inflammation(mm)	
Secondary line of inflammation (mm)	
Other (mm)	In case the question is answered, the user will have to provide a description
Streaks up arm from site	Yes/No question. In case Yes is selected, the user will have to provide a description
Axillary adenopathy	Yes/No question. In case Yes is selected, the user will have to provide measurements and descriptions
Other adenopathy	Yes/No question. In case Yes is selected, the user will have to provide a description
Vaccinia lesions at any other sites	Yes/No question, in case Yes is selected, the user will have to provide a description
Medications prescribed	Yes/No question. If Yes, listing is required
Change in or addition in medication since last visit	
Lab-work drawn	Yes/No question. If No, give reason

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[000133] If the comments tab is selected, the user can use the free text box in FIGURE 22 to add comments about the current day.

Adverse Events

[000134] Once the enrollment and vaccination process has been completed, the IMS 80 application can enable the Adverse Events menu item, as shown in FIGURE 24. This form has Save, Cancel and Print Report buttons. The print report prints an adverse event report in the format of the CDC's VAERS report using the information entered via the IMS 80 application.

Event Details

[000135] The top of the screen in FIGURE 24 has a field that requests entry of the date of onset, and a text box for the event details. A list of categories appears below, but additional possible categories could be added. For each category, a Y/N check box appears and, if checked, additional information is required. For example, the screen in FIGURE 24 can request the following information:

Category (check one or more)	Remarks
Patient died/date patient died	If the checkbox is selected the user will have to enter the date of death.
Life threatening illness	
Resulted in significant disability	
Resulted in permanent disability	
Laboratory Toxicity	
Assessed as serious by the Clinician	
Prolongation of hospitalization	
Congenital Anomaly	
Required hospitalization and number of days of hospitalization	If the checkbox is selected the user will have to enter the number of days in the other column.
Others	If the checkbox is selected, the user will be required to provide a description
Subject Status/Outcome:	
Ongoing	
Resolved without sequelae	If checked, date of resolution is required
Resolved with sequelae	If checked, description and the date of resolution are required.

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Severity (Mark one)
Mild
Moderate
Severe
Life-threatening
Death

Vaccinations and Medication

[000136] This tab on the Adverse Event screen (FIGURE 24) allows the user to enter information about vaccinations the patient received since he got the current vaccination, as well as medication given after the smallpox vaccination, on a form such as that depicted in FIGURE 25.

[000137] The vaccination area has two fields:

- Vaccination Name – Pull-down menu of possible vaccinations
- Vaccination Date – Textbox

[000138] The medication area has the following fields:

- Medication Name – Pull-down menu of possible vaccinations
- Medication Start Date – Textbox
- Medication End Date – Textbox
- Reason

[000139] Next to these fields an Add button can be provided. The user can enter the information and click on the Add button to add the information to a grid that is positioned below the above fields, for example.

Lab Work

[000140] Selecting the Lab Work tab causes the IMS 80 application to generate a screen such as that depicted in FIGURE 26 to allow the user to enter or upload from external sources information about lab work done for the patient. For each lab test, the collection date and results will be entered, along with the normal range for the test. A column indicating an abnormal result (meaning a result not within the normal range) will flag automatically a check mark.

Signature

[000141] A screen (FIGURE 27) can be generated by the IMS 80 application in response to selection of the signature tab which has place for two signatures, that is, one for the person who completed the form and one for the investigator. In addition to the signature boxes, a text box is provided next to each signature box that is pre-populated with the

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username who is logged in to the Tablet PC. The application allows the user to override this name. In addition to these fields, there are two more fields to indicate the date the report was submitted to the IRB and to the FDA, respectively.

Administration

[000142] The following section describes different administrative screens that can be generated by the IMS 80 application.

Clinic Information

[000143] This screen (not shown) allows the user to identify the clinic in which they are working. The user may select the clinic by name or clinic ID. When a clinic is selected the clinic name, ID, address, and phone number is displayed.

Reports

[000144] Data resides in the clinics (e.g., of the IMSs 80 and optionally at a local server 140) and the data center 82. Reports run by the Tablet PC against the data at the clinic will have access to that clinic's data only. Reports run by a separate web application against the data center 82 will have access to data for all clinics in a state, but access to any specific user is based on the access rights of that user.

Clinic Reports

[000145] Each Tablet PC 80 application has the ability to run reports regarding the clinic to which it is connected. The reports can be pre-defined and allow the users to retrieve information they need about the patients and immunization process within the clinic. The reports can be divided into the following types:

- Patient Specific Reports
- Clinic Specific Reports

Patient Specific Reports

[000146] These reports print information about a specific patient. The user will be able to print them as part of the immunization process by clicking on the Print button in a specific form, or by going to a designated reports area and choosing a report to print. Each report will have a default number of copies to be printed, but could be configured by the user. The following table contains the list of available reports. Additional reports could be added.

Report Name	Description
Patient Card	The patient card will have all the

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	information about the patient as entered into the system
Consent Form	This is the consent form printed with the patient signature on it.
Vaccine Adverse Event Report	The pre-defined CDC report.
Patient Web Site Account Information	Information for the patient to use to gain access to the web-based application. Must include patient name, user ID, and password.

Clinic Specific Reports

[000147] These reports present information held at the local clinic for one or more patients. The reports are predefined. The report results can be filtered using predefined parameters. The following table contains the list of potential reports. Additional reports can be added.

Report Name	Description
CDC Vaccinia IND Roster	A daily listing of activity, to be sent to CDC. To be run by a user.
Patients Cards	Up to full patient cards.
Vaccine Adverse Events Summary	
Patients Web Site Account Information	

[000148] Where applicable, the result is a list of all patients that fit these criteria, and by clicking on a specific patient name, the IMS 80 application will open the record. The user also has the option to print a list with these patients' information.

Data Center Reports

[000149] A web-based reporting application allows the user to run predefined reports on data for all clinics in a state. Report results can be filtered using predefined parameters. The authorized user has the ability to view information regarding one or more patients or one or more clinics. The reporting application controls the reports and parameter values available by user group. The following exemplary users groups have been identified:

- Selected clinic personnel
- Selected state personnel
- Selected national personnel
- Selected call center and system administration personnel

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[000150] Members of the selected clinic personnel group will preferably only be able to see data on particular patients from their clinic, unless the user has access-rights to information regarding other patients.

[000151] The following table lists reports that are representative of reports available from the data center 82.

Report Name/Type	Description
Comparisons Reports	<p>These reports will allow the user to compare between 2 or more clinics, or between a clinic and the average of all other clinics on a set of various parameters, such as:</p> <ul style="list-style-type: none"> • number of vaccination given per day • Progress pace – the user will be able to define a comparison unit (hour, day, week etc.) and to see the progress pace for a specific clinic and the comparisons between 2 or more clinics. <p>The reports will be available both in absolute number and in a graphic display.</p>
Patient Reports	<p>These reports will display all the information available in the system for a group of patients.</p>
Data Reports	<p>These reports will allow the user to analyze the information stored in the database, based on various parameters and criteria.</p> <p>For example, the user will be able to see a report that will display in a graph form the average size of the lesion on day 5, where each data point represents the average in a clinic.</p> <p>Such reports will be available for each numeric data stored in the database. The user will have the ability to compare the values to the overall values and to see abnormalities in groups of patients/clinics.</p>

Global Administration

[000152] An administrator at the data center 82 can perform the following tasks:

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- add, delete, and change users
- change username password
- disable existing users
- add new clinic
- distribute new software versions
- distribute changes to the database schema

[000153] These operations are preferably done by an authorized user with access to the entire database 122 and can be pushed to each clinic connected to the internet. FIGURES 28 and 29 illustrate exemplary administration screens generated, for example, at the IMS 80 or the data center 82 to configure IMS 80 application settings.

Web Access to Patient Diary

[000154] During the enrollment and vaccination process, each patient receives at the clinic a user ID and a password. The user ID can be the clinic ID and an internal user ID which the application auto naturally generates, and a password (e.g., automatically generated by the system 10) for each patient.

[000155] In order to allow a patient to enter his/her diary report via a web-browser, the system provides a web application that enables patients to login and enter the information. Each patient is able to login to a designated website using the username and password received. Following authentication, he has access to the diary cards as defined above. The information is recorded at the data center 82 and synchronized with the associated clinic.

[000156] It should be understood the processes described are only exemplary and any suitable permutation of the processes may be used. The foregoing disclosure and description of the invention is illustrative and explanatory thereof and various changes to the size, shape, materials, components, and order may be made without departing from the spirit of the invention. While the present invention has been described with reference to the disclosed embodiments, it is to be readily apparent to those of ordinary skill in the art that changes and modifications to the form in details may be made without departing from the spirit and scope of the invention.

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AMENDED CLAIMS

[received by the International Bureau on 02 December 2003 (02.12.03);
original claim 2 amended; new claims 13-44 added; remaining claims unchanged]

1. A method of collecting and storing immunization data for a patient comprising the steps of:
running an application on a computer at a vaccination site for entering patient information selected from the group consisting of name, age, gender, address, medical history, medications in use by said patient, occupation, and previous vaccination data;
storing said patient information as an electronic patient record;
generating information relating to a vaccination for review by said patient;
obtaining patient consent to receive said vaccination by generating an electronic consent agreement and storing said patient's digital signature acknowledging acceptance; and
entering new vaccination data relating to said vaccination into said electronic patient record when said vaccination is administered to said patient.
2. A method as claimed in claim 1 comprising the steps of:
generating a digital image of a vaccination location on said patient; and
storing said digital image in said electronic patient record.
3. A method as claimed in claim 1 comprising the steps of:
entering disease information comprising symptoms experienced by said patient; and
storing said disease information in said electronic patient record.
4. A method as claimed in claim 3, wherein said disease information relates to smallpox symptoms.
5. A method as claimed in claim 4 comprising the steps of:
generating a digital image of a smallpox lesion site on said patient; and
storing said digital image in said electronic patient record.
6. A method as claimed in claim 1 comprising the steps of:
storing said electronic patient record with said electronic patient record corresponding to each of a plurality of patients into a database; and
synchronizing changes made to any said electronic patient record at a remote site with the corresponding said electronic patient record in said database to update said database.
7. A method as claimed in claim 6 comprising the steps of:
entering disease information comprising symptoms experienced by any of said plurality of patients;

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storing said disease information in the corresponding said electronic patient record.

8. A method as claimed in claim 7, wherein said disease information relates to smallpox symptoms and said database is accessible by personnel selected from the groups consisting of a disease control center, a state government office, a federal government office, a medical center.

9. A method as claimed in claim 1, wherein said patient can access said electronic patient record using at least one of a web browser and a telephone transaction.

10. A method as claimed in claim 6 comprising the steps of:
entering adverse effects information comprising symptoms experienced by any of said plurality of patients following said vaccination;
storing said adverse effects information in the corresponding said electronic patient record.

11. A method as claimed in claim 10, wherein said adverse effects information relates to smallpox vaccination and said database is accessible by personnel selected from the groups consisting of a disease control center, a state government office, a federal government office, and a medical center.

12. A method as claimed in claim 1 comprising the step of running a recommendation engine on said computer to determine if said patient is eligible to have said vaccination based on said patient information and data relating to effects of said vaccination.

13. A method as claimed in claim 1, wherein said generating step comprises the step of generating at least one of a vaccination information statement or VIS and answers to frequently asked questions or FAQs relating to said vaccination.

14. A method of determining a recommendation for vaccination for a patient comprising the steps of:

receiving patient information selected from the group consisting of name, age, gender, medical history, vaccination history, health status, medications in use by the patient, occupation, and travel plans;

receiving vaccination data relating to at least one of actual effects and potential effects of the vaccination;

determining a health risk to patient for receiving the vaccination based on said patient information and said vaccination data; and

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generating a recommendation regarding vaccination based on said health risk.

15. A method as claimed in claim 14, wherein said generating step comprises the step of generating a risk-based exemption from receiving the vaccination when said health risk is determined to exceed a predetermined level.

16. A method of collecting and storing immunization and disease information comprising the steps of:

running an application on a computer at a vaccination site for entering patient information selected from the group consisting of name, age, gender, address, medical history, medications in use by said patient, occupation, and previous vaccination data;

storing said patient information as an electronic patient record;

entering disease information comprising symptoms experienced by said patient;

storing said disease information in said electronic patient record;

generating a digital image of a disease symptom appearing on said patient; and

storing said digital image in said electronic patient record.

17. A method as claimed in claim 16, wherein said disease information relates to smallpox symptoms.

18. A method as claimed in claim 17 wherein said generating step for generating said digital image comprises the step of generating a digital image of a smallpox lesion site on said patient.

19. A method as claimed in claim 16, wherein said application is programmed to allow said patient to generate and store diary entries on respective dates relating to said symptoms in said electronic patient record.

20. A method of collecting and storing immunization data comprising:

running an application on a computer at a vaccination site for entering patient information selected from the group consisting of name, age, gender, address, medical history, medications in use by said patient, occupation, and previous vaccination data;

storing said patient information as an electronic patient record;

entering via said application adverse event information comprising adverse side effects experienced by said patient following vaccination; and

storing said adverse event information in said electronic patient record.

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21. A method as claimed in claim 20 further comprising the step of storing said electronic patient record in a database.

22. A method as claimed in claim 20, wherein said application is programmable to generate screens to guide users when entering said adverse event information to comply with protocols for documenting adverse events to vaccines.

23. A method as claimed in claim 22, wherein said application is programmable to collect and store documentation of said adverse events in compliance with a protocol set forth by at least one of the Center for Disease Control and the National Institutes of Health.

24. A method as claimed in claim 20, wherein said application is programmable to generate at least one screen to guide a user when making diary entries on respective dates relating to said adverse side effects in said electronic patient record.

25. A method of collecting and storing immunization data comprising the steps of:
establishing at least one ad-hoc network comprising at least one immunization mobile station in communication with a data center, said data center being configured to store disease information and vaccination information relating, respectively, to a vaccine preventable disease and vaccine therefor;

providing at least one of said disease information and said vaccination information at said immunization mobile station if requested;

presenting at least one of said disease information and said vaccination information to patients receiving a vaccination via said immunization mobile station if requested;

configuring said immunization mobile station with at least one application for collecting and storing patient data and vaccination administration data relating to patients receiving a vaccination administered at a location remote with respect to said data center;

generating electronic patient records comprising said patient data and said vaccination administration data; and

transmitting said electronic patient records to said data center for storage in a database.

26. A method as claimed in claim 25 further comprising the steps of:

determining a health risk to a patient for receiving a vaccination based on said patient data and said vaccination information; and

generating a recommendation regarding vaccination based on said health risk.

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27. A method as claimed in claim 25 further comprising the steps of:
generating a digital image of a symptom appearing on a patient; and
storing said digital image in one of said electronic patient records corresponding to
the patient.
28. A method as claimed in claim 27, wherein said symptom is a smallpox lesion.
29. A method as claimed in claim 25 further comprising the steps of:
generating adverse event data relating to adverse side effects of a vaccination
experienced by a patient using said application; and
storing said adverse event data in one of said electronic patient records corresponding
to the patient.
30. A method as claimed in claim 29, wherein said application is programmable to
generate screens to guide users when entering said adverse event data to comply with
protocols for documenting adverse events to vaccines.
31. A method as claimed in claim 30, wherein said application is programmable to collect
and store said adverse events data in compliance with a protocol set forth by at least one of
the Center for Disease Control and the National Institutes of Health.
32. A method as claimed in claim 25, wherein said application is programmed to allow
said patient to generate and store diary entries on respective dates relating to said symptoms
in said electronic patient record.
33. A method as claimed in claim 25 further comprising at least one other immunization
mobile station in peer-to-peer wireless communication with said immunization mobile station.
34. A system for managing immunization and disease information comprising:
a database for storing disease information, vaccination information, electronic patient
records, and vaccine administration data;
a service provider transaction module for receiving service provider input data
selected from the group consisting of biographical patient information corresponding to
patients receiving vaccinations, patient medical history, vaccination date, vaccination lot
number, location of vaccination administration, adverse event data relating to an adverse
reaction to a vaccine, said service provider input data being stored in corresponding said
electronic patient records and being used to generate said vaccine administration data, and

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transmitting output data from said database to service providers, said output data being selected from the group consisting of said disease information, said vaccination information, and said electronic patient records, said disease information and said vaccination information comprising, respectively, information about a vaccine preventable disease and the vaccine therefor; and

a customer transaction module for providing at least one of said vaccination administration data and said disease information to a customer upon request, said vaccination administration data comprising tracking data to identify which of said patients in a selected group have been vaccinated with a selected vaccine, said disease information comprising symptoms being experienced by said patients and documented in said electronic patient records.

35. A system as claimed in claim 34, wherein said customer is selected from the group consisting of a government, a state government, a national government, a hospital, a health clinic, a call center, a retailer, a pharmacy, a corporation, an employer, a regulatory group, a government agency, and a disease control center.

36. A system as claimed in claim 34, wherein said customer transaction module is operable to provide said disease information to said customer for epidemic evaluation and control.

37. A system as claimed in claim 34, wherein said customer transaction module is operable to provide said vaccination administration information to said customer for determining compliance with regulatory requirements relating to vaccinations.

38. A system as claimed in claim 34, wherein said system is implemented by said customer for bio-terrorism preparedness.

39. A system as claimed in claim 34 further comprising a patient transaction module for providing a patient with at least one of said disease information, said vaccination information and his corresponding one of said electronic patient records, and for receiving patient input data selected from the group consisting of biographical patient information, patient medical history, vaccination history, and adverse reaction data.

40. A system as claimed in claim 34 further comprising at least one remote processing device programmable to collect and store said service provider input data.

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41. A system as claimed in claim 40, wherein said remote processing device comprises an application program to generate Center for Disease Control Vaccine Adverse Event Reports with data from at least one of said electronic patient records and said vaccination administration data.
42. A system as claimed in claim 34, wherein clinic-specific information is generated using said vaccination administration data in said database to generate clinic reports regarding vaccinations occurring there.
43. A system as claimed in claim 42, wherein said clinic-specific information is selected from the group consisting of a Center for Disease Control Vaccinia IND Roster listing clinic activity, said electronic patient records of patients who visited the clinic, and a summary of vaccine adverse events.
44. A system as claimed in claim 42, wherein said clinic-specific information for a plurality of clinics is retrieved from said vaccination administration data in said database to generate reports regarding multiple vaccination administration locations.

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storing said disease information in the corresponding said electronic patient record.

8. A method as claimed in claim 7, wherein said disease information relates to smallpox symptoms and said database is accessible by personnel selected from the groups consisting of a disease control center, a state government office, a federal government office, a medical center.

9. A method as claimed in claim 1, wherein said patient can access said electronic patient record using at least one of a web browser and a telephone transaction.

10. A method as claimed in claim 6 comprising the steps of:
entering adverse effects information comprising symptoms experienced by any of said plurality of patients following said vaccination;
storing said adverse effects information in the corresponding said electronic patient record.

11. A method as claimed in claim 10, wherein said adverse effects information relates to smallpox vaccination and said database is accessible by personnel selected from the groups consisting of a disease control center, a state government office, a federal government office, and a medical center.

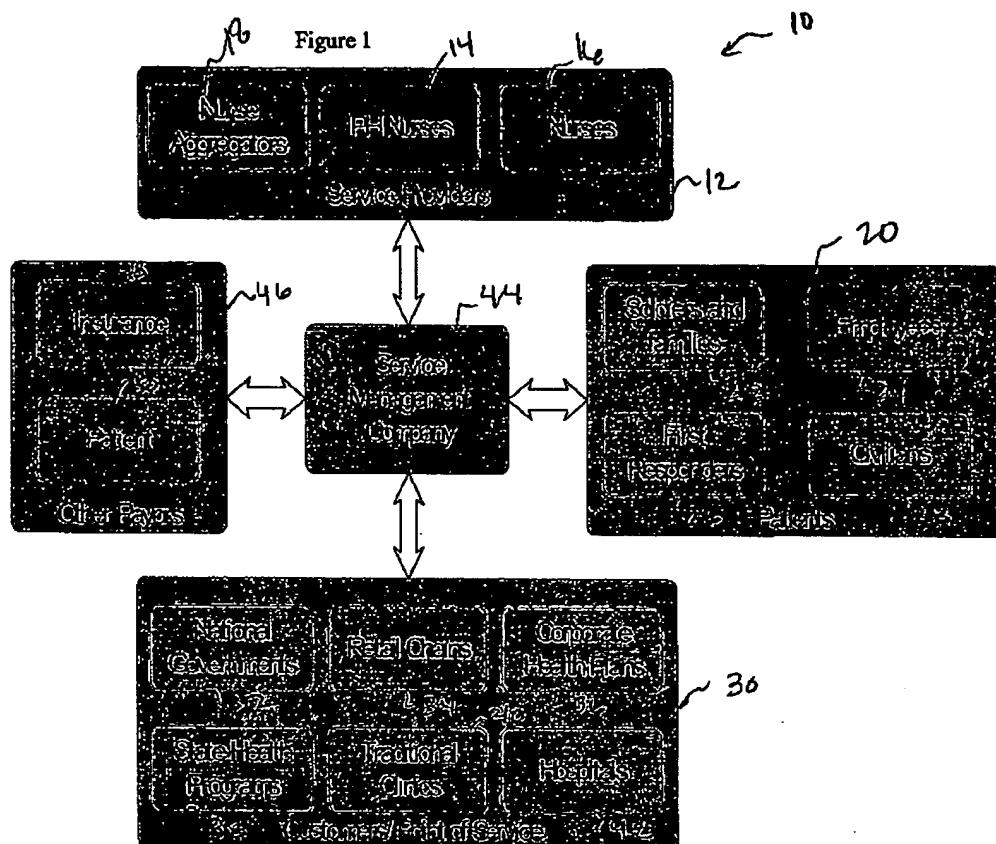
12. A method as claimed in claim 1 comprising the step of running a recommendation engine on said computer to determine if said patient is eligible to have said vaccination based on said patient information and data relating to effects of said vaccination.

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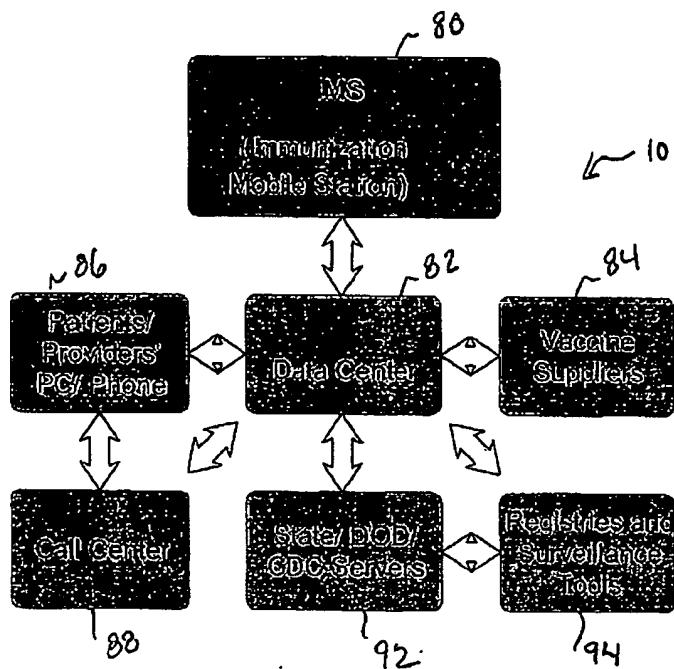
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Figure 2



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FIGURE 3

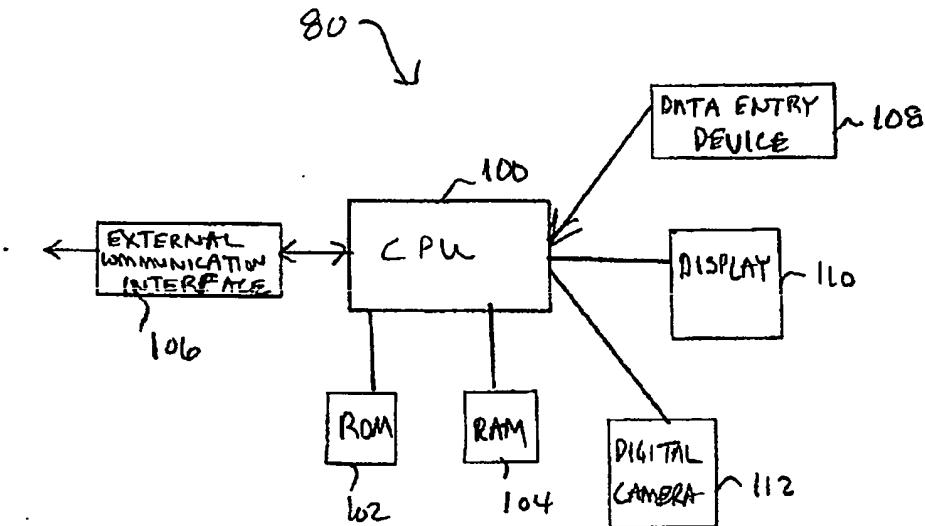
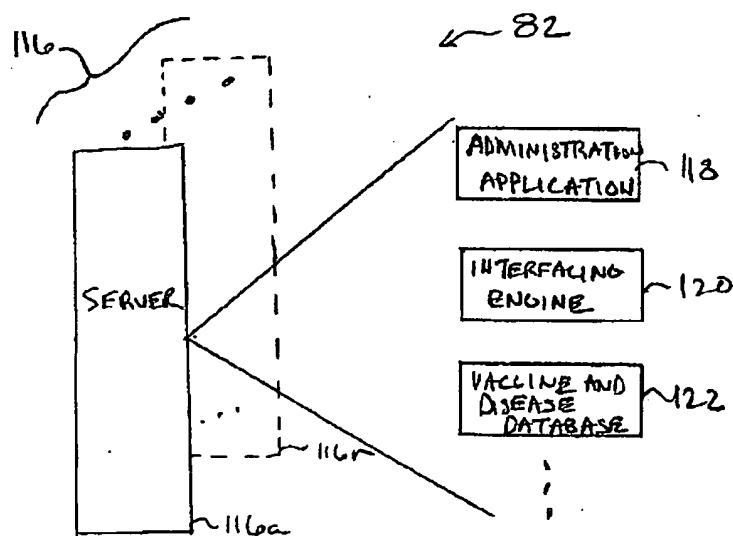


FIGURE 4



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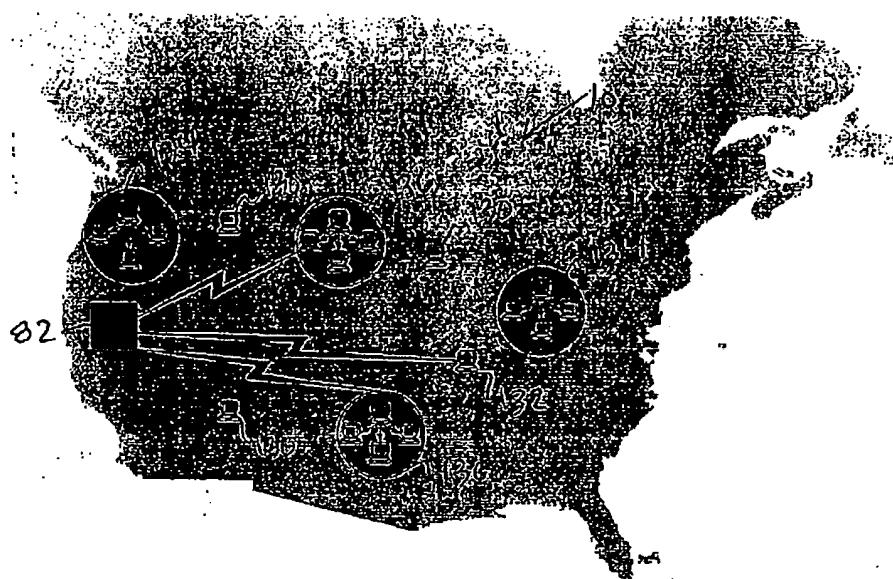


FIGURE 5.

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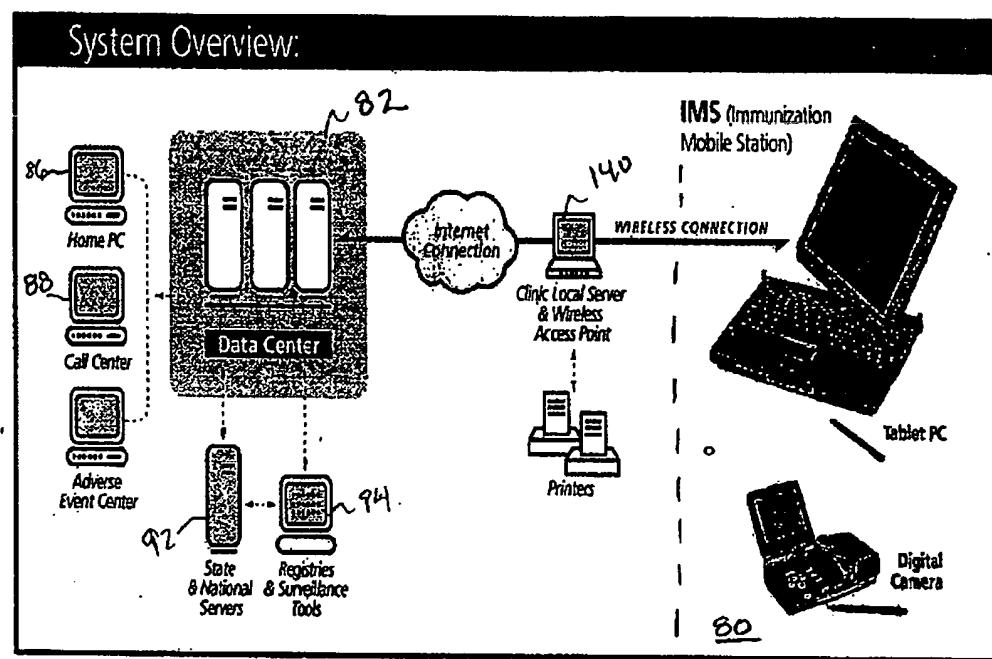


FIGURE 6

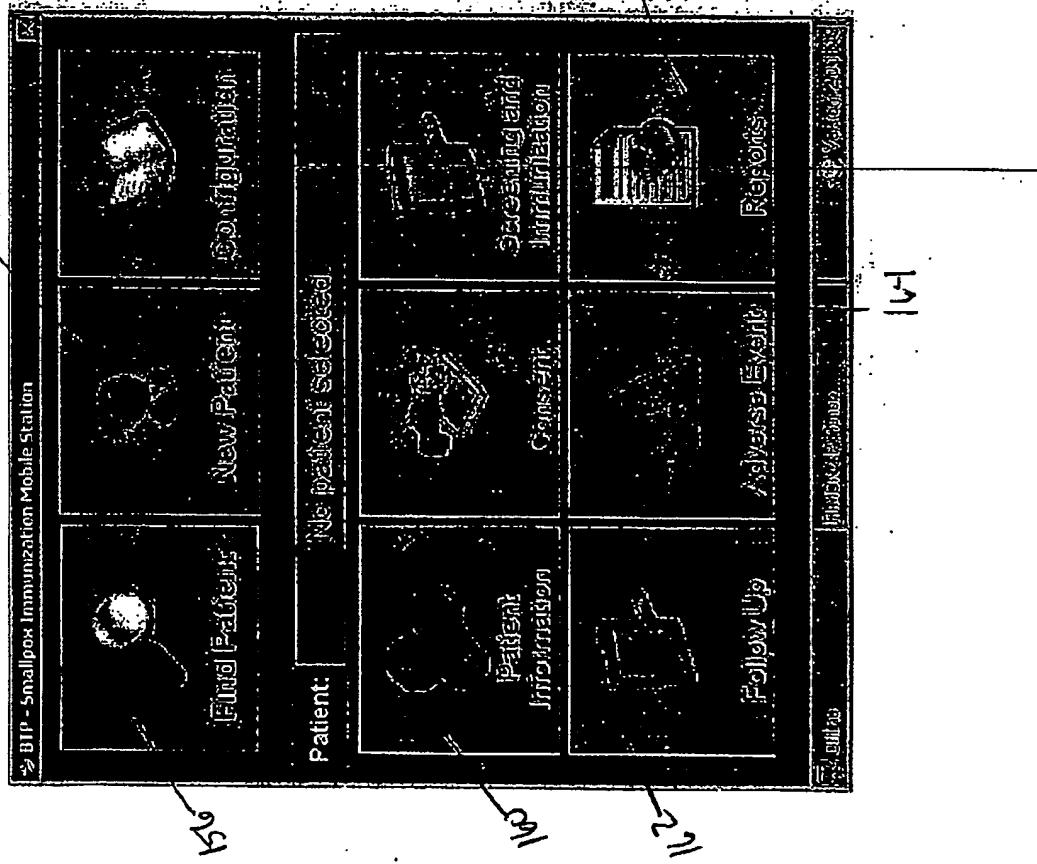
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FIGURE 7



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Find Patient

Find Patient

Search Criteria

Name _____
Date _____
Medical Record Number _____
Patient Name _____
Patient ID _____
Patient Address _____

Search

Search Results

View Cancel

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FIGURE 8

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Figure 9

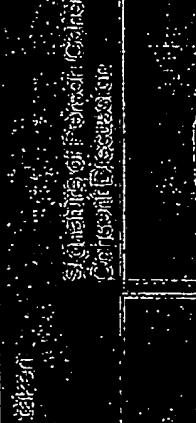
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FIGURE 10

Consent to Smallpox Vaccination <input checked="" type="checkbox"/> I consent to vaccination					
SMALLPOX VACCINATION INFORMED CONSENT					
Participant Informed Consent Signature for Vaccination:					
I HAVE: <ul style="list-style-type: none"> • Viewed the vaccine informational video or read the video script in the packet; or talked with a translator. • Received the information packet which includes information on benefits, risks, side effects, risks to contacts, precautions for vaccination and adverse events, care of my vaccination site, what to do in case of illness, and contact information for problems or questions. • Completed the medical screening questionnaire. • Received counseling and additional information if I was identified as having any possible contraindications. • Had the opportunity to have my questions answered. • Understood that participation is voluntary and that I have the right to refuse. • Agreed to photography of my face and vaccination site. 					
<p><input checked="" type="checkbox"/> I have been informed of the risks and benefits associated with vaccination and based on the information provided, I am willing to undergo vaccination.</p> <p><input type="checkbox"/> I understand that I will be asked to provide a photograph of my face and vaccination site.</p> <p><input type="checkbox"/> I understand that I will be asked to sign a consent form.</p>					
<p>Smallpox Vaccination Signature:</p> <div style="text-align: center;">  Rimon Erez </div>					
<table border="1" style="width: 100%; text-align: center;"> <tr> <td style="width: 50%;">Date:</td> <td style="width: 50%;">Page:</td> </tr> <tr> <td>09/28/2004</td> <td>54</td> </tr> </table>		Date:	Page:	09/28/2004	54
Date:	Page:				
09/28/2004	54				

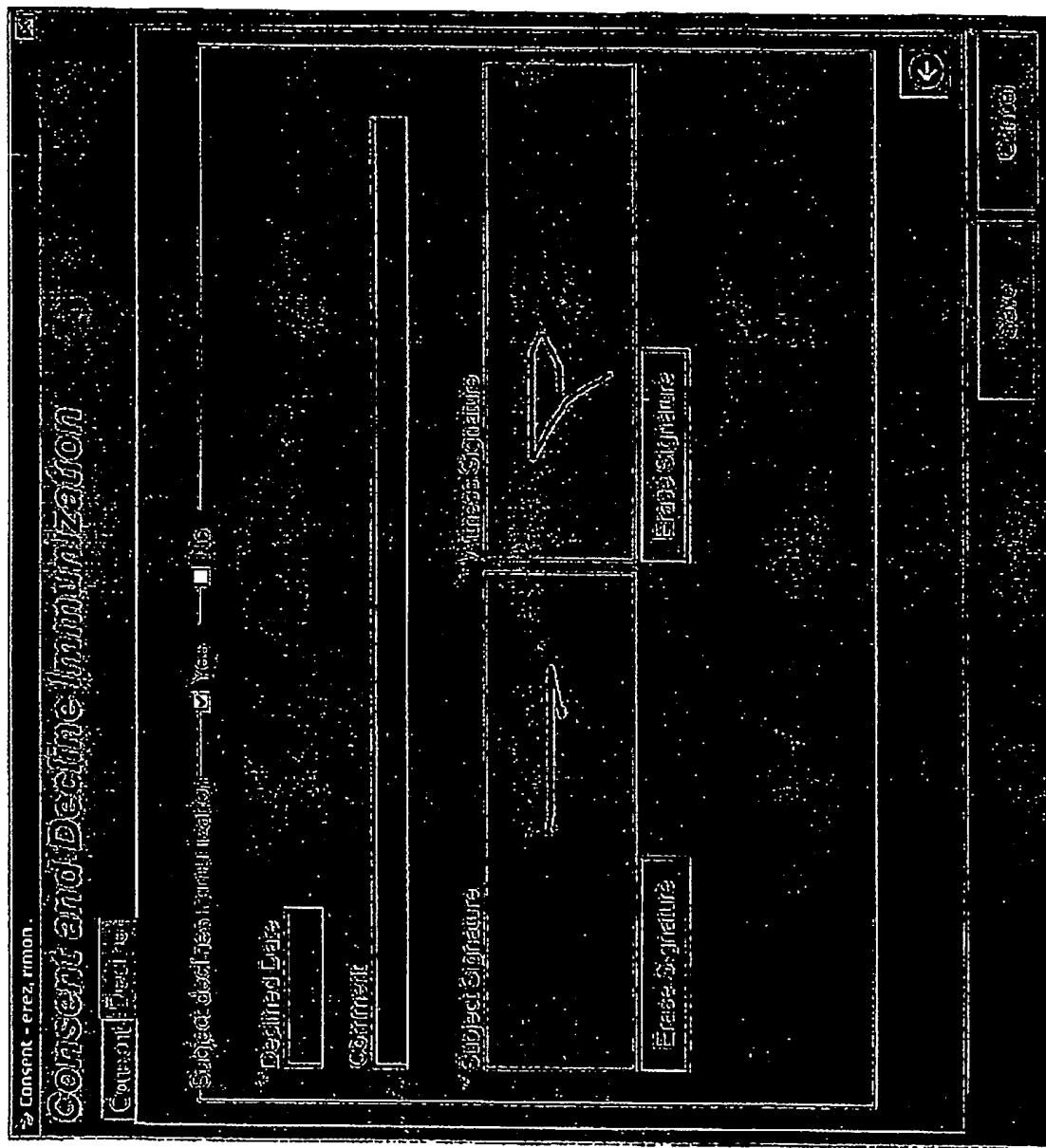
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FIGURE 11



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FIGURE 12

Question	பதிலாகவே என்று விடும் பொருள்	பதிலாகவே என்று விடும் பொருள்	பதிலாகவே என்று விடும் பொருள்
Allergy to any medications	No	No	No
Allergy to Streptomycin	No	No	No
Allergy to Neomycin	No	No	No
Allergy to Chlortetracycline	No	No	No
Allergy to Polymyxin B	No	No	No
Allergy to Phenol	No	No	No
Adhesive reaction to shellac/vaccine in the past	No	No	No
Using breath inhaler for asthma or respiratory system	No	No	No
Using oral, inhaled or topical steroids	No	No	No
Taking chemotherapy/medications	No	No	No
Cancer or leukemia	No	No	No
AIDS or HIV	No	No	No
Current or past eczema or atopic dermatitis	No	No	No
Sickle Cell Anemia (not including Sickle Trait)	No	No	No
Spleen injury or removal	No	No	No
Organ transplant or taking anti-rejection drugs	No	No	No
Autoimmune disorder (RA, SLE, Scleroderma)	No	No	No
Multiple Sclerosis or Vasculitis	No	No	No
Burns, rashes, open wounds, or herpes (currently active)	No	No	No

அதிகாரி பேரவை அல்லது முனிசிபல் துணிகள் அல்லது நிலை நிலை விதிகள்

பதிலாகவே என்று விடும் பொருள் பதிலாகவே என்று விடும் பொருள்

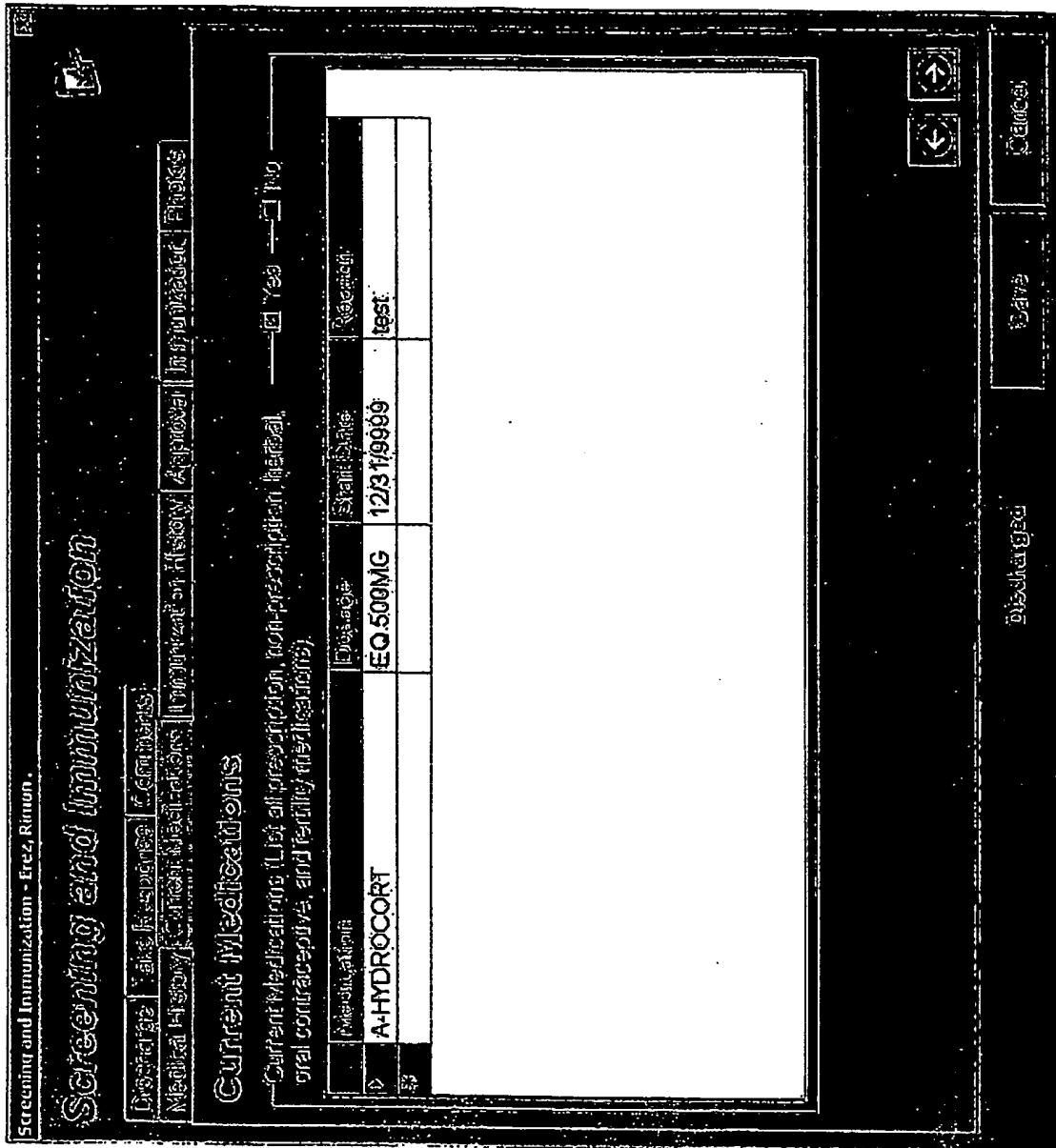
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FIGURE 13



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FIGURE I

Date of birth (DD/MM/YYYY)		Name of the child		Mother's name	
05/12/1999		Amitabh		Shobha Devi	
Gender		Date of birth		Mother's age	
Male		05/12/1999		35	
Mother's name		Father's name		Guardian	
Shobha Devi		Rakesh Kumar		Sister	
Mother's address		Father's address		Guardian address	
Kanpur, Uttar Pradesh, India		Kanpur, Uttar Pradesh, India		Kanpur, Uttar Pradesh, India	
Mobile number		Mobile number		Mobile number	
9898989898		9898989898		9898989898	
Childhood		Not take		Recall	
05		12319999			

Childhood Immunization Status:

Date	Vaccine	Site	Remarks
14/12/2022	Antigen	By Mouth	1

Other Vaccines Given:

Date	Vaccine	Site	Remarks

Other Information:

Reason for visit	Age at visit	Referring Doctor

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FIGURE 1.

Screening and Immunization - Free, Rimon.									
<p>Current Medications</p> <p>ANTIDRUG REPORT</p> <p>Medical History</p> <p>None</p>									
<p>Previous Vaccinations</p> <table border="1"> <tr> <td>Smallpox</td> <td>12311999</td> <td>Age: 0-5</td> <td>Response: No take</td> </tr> <tr> <td>Antitoxin</td> <td>11111952</td> <td>Remarks: 1</td> <td></td> </tr> </table>		Smallpox	12311999	Age: 0-5	Response: No take	Antitoxin	11111952	Remarks: 1	
Smallpox	12311999	Age: 0-5	Response: No take						
Antitoxin	11111952	Remarks: 1							
<p>Dosage: EQ 600MG:BASEMENT</p> <p>Reason/ test</p>									
<p>Physical Exam</p> <p>Signs & Symptoms</p> <p>Findings</p>									
<p>Patient is free from disease</p> <p>Signature:</p>									
<p>Printed Name:</p>									
<p>Date:</p>									
<p>Printed Name:</p>									
<p>Date:</p>									

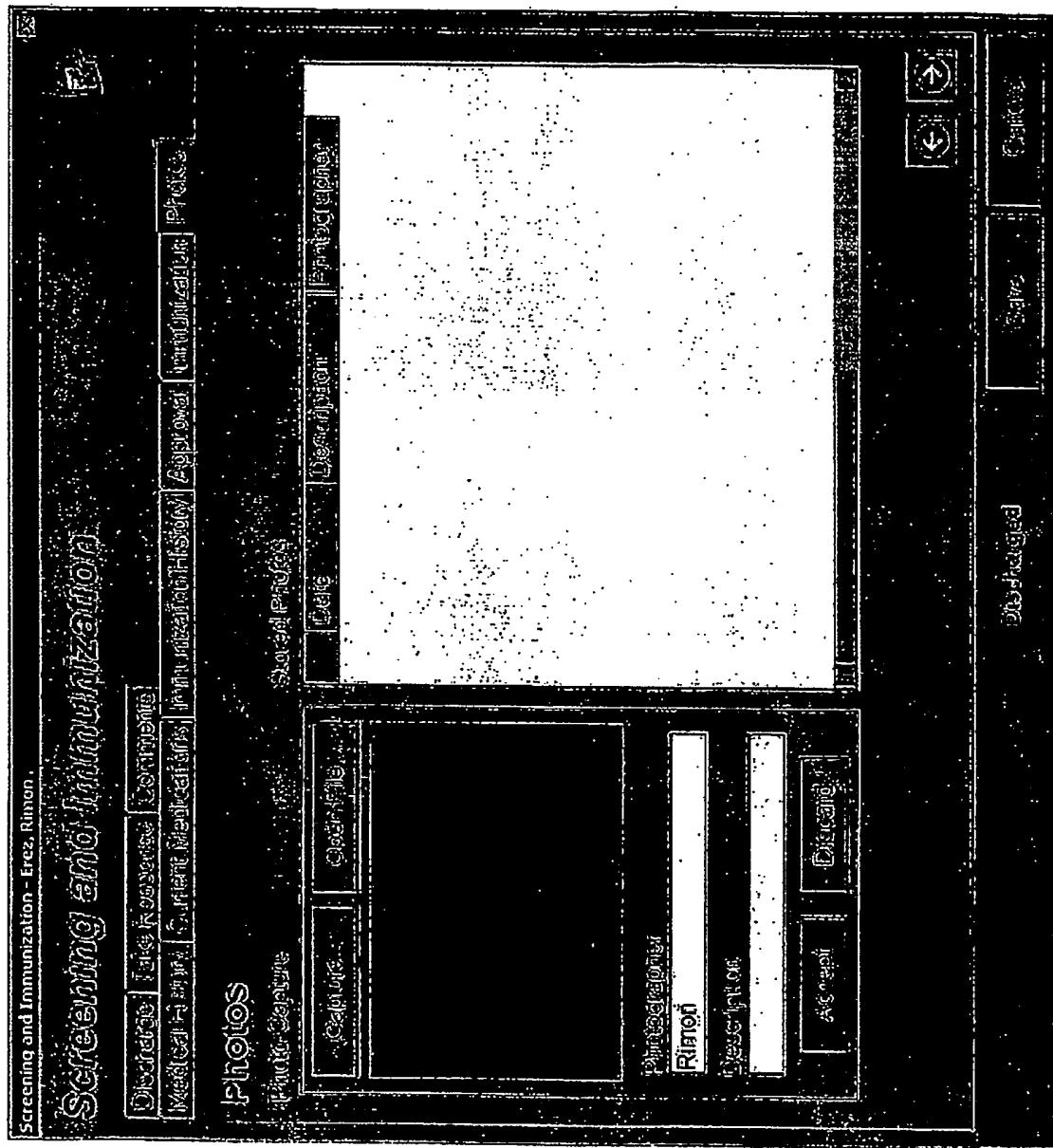
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FIGURE 16



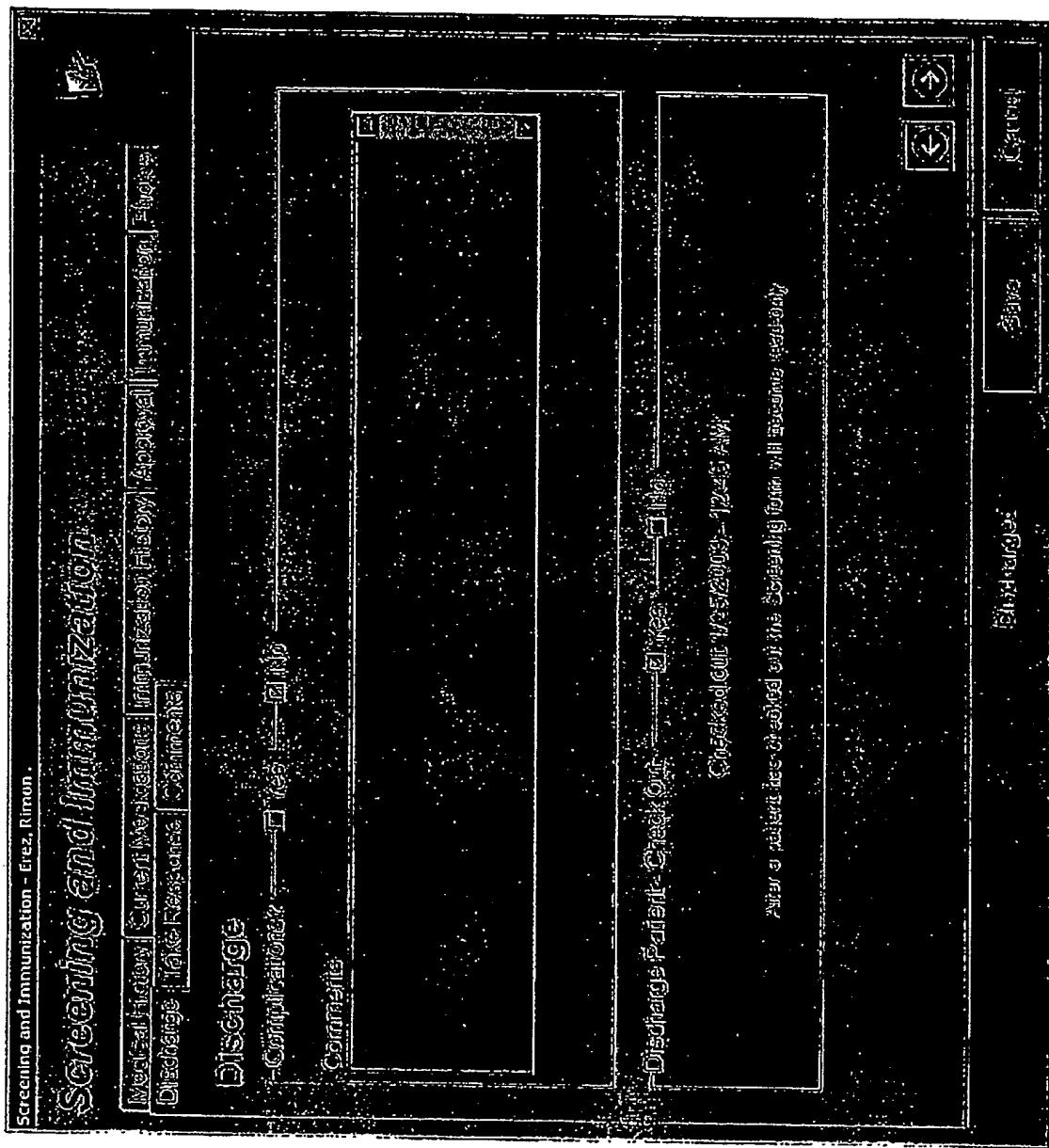
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FIGURE 17



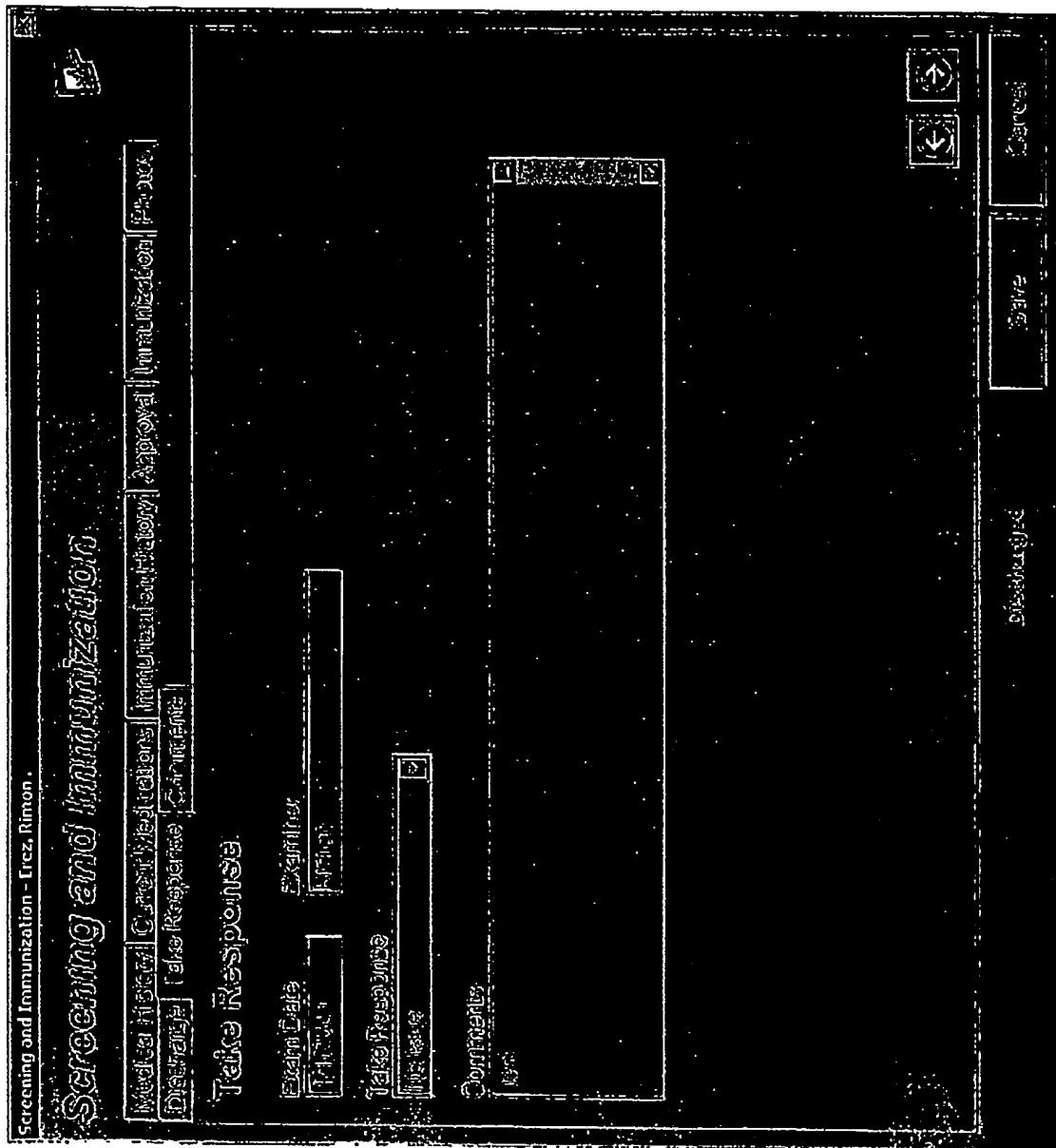
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Figure 1



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FIGURE 1



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Figure 2c

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FIGURE 21

Follow Up - Day 1		Day 2																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																					
Pre-vaccination	Post-vaccination	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21	22	23	24	25	26	27	28	29	30	31	32	33	34	35	36	37	38	39	40	41	42	43	44	45	46	47	48	49	50	51	52	53	54	55	56	57	58	59	60	61	62	63	64	65	66	67	68	69	70	71	72	73	74	75	76	77	78	79	80	81	82	83	84	85	86	87	88	89	90	91	92	93	94	95	96	97	98	99	100	101	102	103	104	105	106	107	108	109	110	111	112	113	114	115	116	117	118	119	120	121	122	123	124	125	126	127	128	129	130	131	132	133	134	135	136	137	138	139	140	141	142	143	144	145	146	147	148	149	150	151	152	153	154	155	156	157	158	159	160	161	162	163	164	165	166	167	168	169	170	171	172	173	174	175	176	177	178	179	180	181	182	183	184	185	186	187	188	189	190	191	192	193	194	195	196	197	198	199	200	201	202	203	204	205	206	207	208	209	210	211	212	213	214	215	216	217	218	219	220	221	222	223	224	225	226	227	228	229	230	231	232	233	234	235	236	237	238	239	240	241	242	243	244	245	246	247	248	249	250	251	252	253	254	255	256	257	258	259	260	261	262	263	264	265	266	267	268	269	270	271	272	273	274	275	276	277	278	279	280	281	282	283	284	285	286	287	288	289	290	291	292	293	294	295	296	297	298	299	300	301	302	303	304	305	306	307	308	309	310	311	312	313	314	315	316	317	318	319	320	321	322	323	324	325	326	327	328	329	330	331	332	333	334	335	336	337	338	339	340	341	342	343	344	345	346	347	348	349	350	351	352	353	354	355	356	357	358	359	360	361	362	363	364	365	366	367	368	369	370	371	372	373	374	375	376	377	378	379	380	381	382	383	384	385	386	387	388	389	390	391	392	393	394	395	396	397	398	399	400	401	402	403	404	405	406	407	408	409	410	411	412	413	414	415	416	417	418	419	420	421	422	423	424	425	426	427	428	429	430	431	432	433	434	435	436	437	438	439	440	441	442	443	444	445	446	447	448	449	450	451	452	453	454	455	456	457	458	459	460	461	462	463	464	465	466	467	468	469	470	471	472	473	474	475	476	477	478	479	480	481	482	483	484	485	486	487	488	489	490	491	492	493	494	495	496	497	498	499	500	501	502	503	504	505	506	507	508	509	510	511	512	513	514	515	516	517	518	519	520	521	522	523	524	525	526	527	528	529	530	531	532	533	534	535	536	537	538	539	540	541	542	543	544	545	546	547	548	549	550	551	552	553	554	555	556	557	558	559	560	561	562	563	564	565	566	567	568	569	570	571	572	573	574	575	576	577	578	579	580	581	582	583	584	585	586	587	588	589	590	591	592	593	594	595	596	597	598	599	600	601	602	603	604	605	606	607	608	609	610	611	612	613	614	615	616	617	618	619	620	621	622	623	624	625	626	627	628	629	630	631	632	633	634	635	636	637	638	639	640	641	642	643	644	645	646	647	648	649	650	651	652	653	654	655	656	657	658	659	660	661	662	663	664	665	666	667	668	669	670	671	672	673	674	675	676	677	678	679	680	681	682	683	684	685	686	687	688	689	690	691	692	693	694	695	696	697	698	699	700	701	702	703	704	705	706	707	708	709	710	711	712	713	714	715	716	717	718	719	720	721	722	723	724	725	726	727	728	729	730	731	732	733	734	735	736	737	738	739	740	741	742	743	744	745	746	747	748	749	750	751	752	753	754	755	756	757	758	759	760	761	762	763	764	765	766	767	768	769	770	771	772	773	774	775	776	777	778	779	770	771	772	773	774	775	776	777	778	779	780	781	782	783	784	785	786	787	788	789	790	791	792	793	794	795	796	797	798	799	800	801	802	803	804	805	806	807	808	809	8010	8011	8012	8013	8014	8015	8016	8017	8018	8019	8020	8021	8022	8023	8024	8025	8026	8027	8028	8029	8030	8031	8032	8033	8034	8035	8036	8037	8038	8039	8040	8041	8042	8043	8044	8045	8046	8047	8048	8049	8050	8051	8052	8053	8054	8055	8056	8057	8058	8059	8060	8061	8062	8063	8064	8065	8066	8067	8068	8069	8070	8071	8072	8073	8074	8075	8076	8077	8078	8079	8080	8081	8082	8083	8084	8085	8086	8087	8088	8089	8090	8091	8092	8093	8094	8095	8096	8097	8098	8099	80100	80101	80102	80103	80104	80105	80106	80107	80108	80109	80110	80111	80112	80113	80114	80115	80116	80117	80118	80119	80120	80121	80122	80123	80124	80125	80126	80127	80128	80129	80130	80131	80132	80133	80134	80135	80136	80137	80138	80139	80140	80141	80142	80143	80144	80145	80146	80147	80148	80149	80150	80151	80152	80153	80154	80155	80156	80157	80158	80159	80160	80161	80162	80163	80164	80165	80166	80167	80168	80169	80170	80171	80172	80173	80174	80175	80176	80177	80178	80179	80180	80181	80182	80183	80184	80185	80186	80187	80188	80189	80190	80191	80192	80193	80194	80195	80196	80197	80198	80199	80200	80201	80202	80203	80204	80205	80206	80207	80208	80209	80210	80211	80212	80213	80214	80215	80216	80217	80218	80219	80220	80221	80222	80223	80224	80225	80226	80227	80228	80229	80230	80231	80232	80233	80234	80235	80236	80237	80238	80239	80240	80241	80242	80243	80244	80245	80246	80247	80248	80249	80250	80251	80252	80253	80254	80255	80256	80257	80258	80259	80260	80261	80262	80263	80264	80265	80266	80267	80268	80269	80270	80271	80272	80273	80274	80275	80276	80277	80278	80279	80280	80281	80282	80283	80284	80285	80286	80287	80288	80289	80290	80291	80292	80293	80294	80295	80296	80297	80298	80299	80300	80301	80302	80303	80304	80305	80306	80307	80308	80309	80310	80311	80312	80313	80314	80315	80316	80317	80318	80319	80320	80321	80322	80323	80324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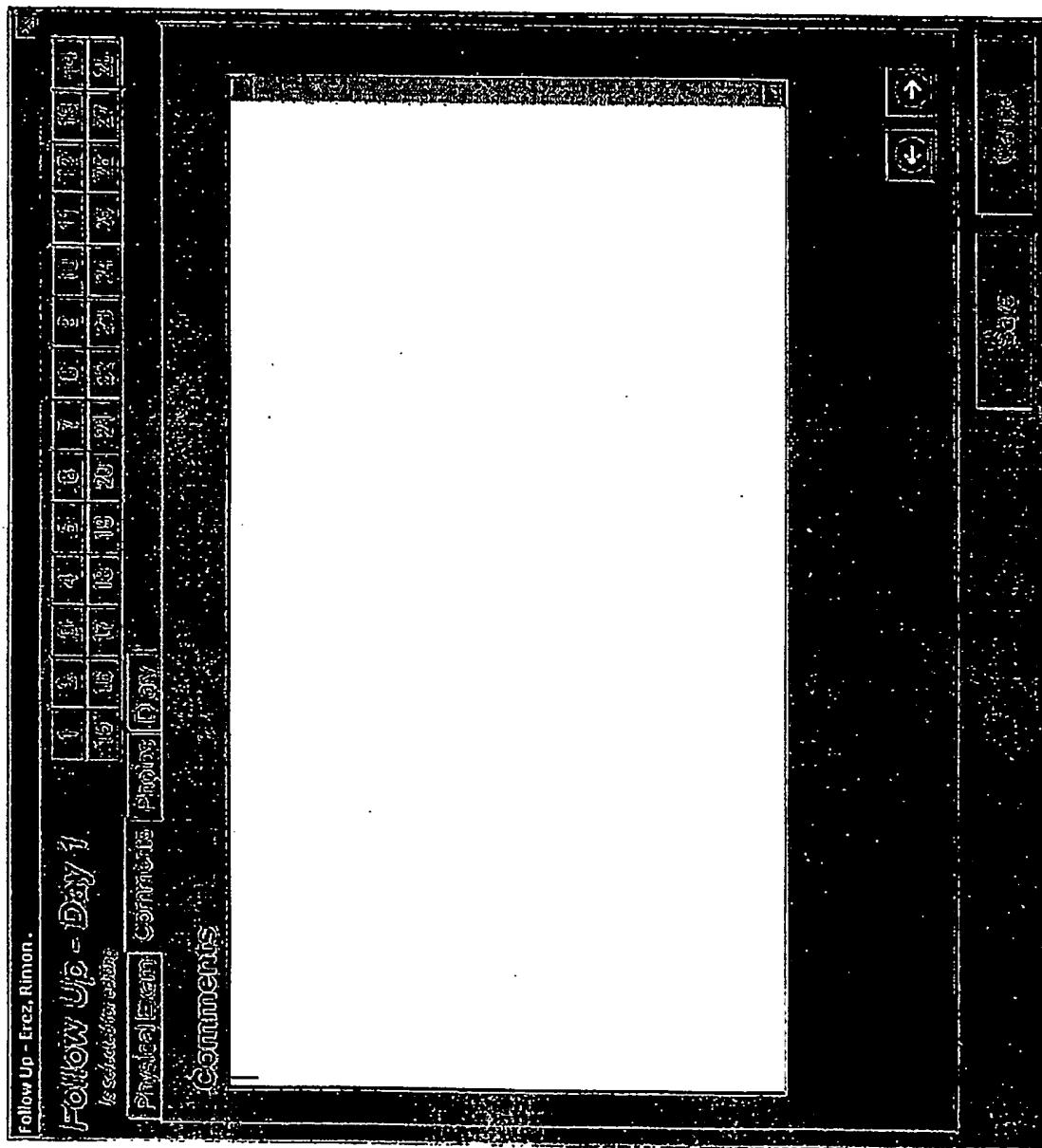
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FIGURE 72



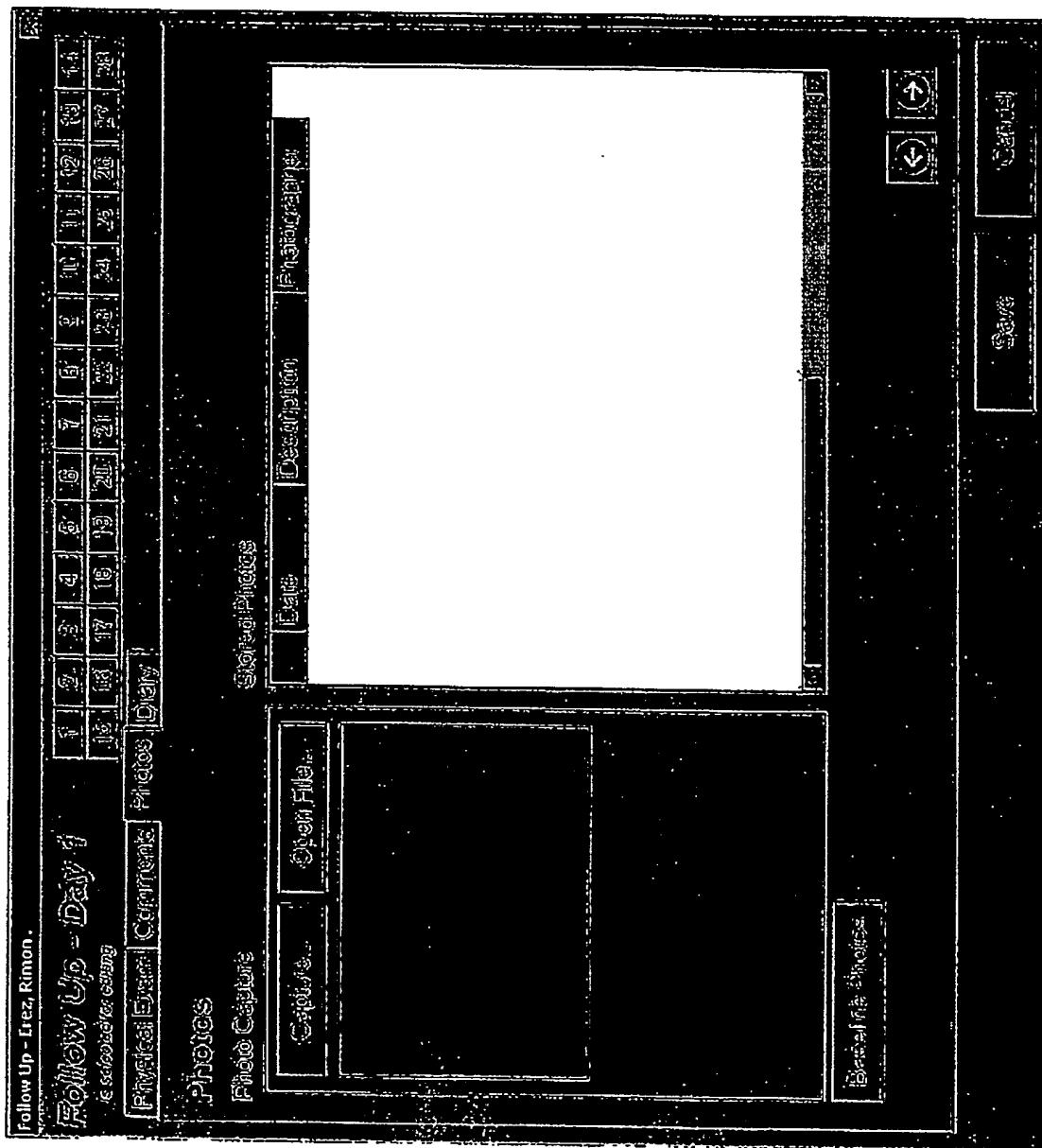
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FIGURE 2-3



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FIGURE 24

Adverse Event Report Event Category: <input checked="" type="checkbox"/> Clinical <input type="checkbox"/> Manufacturing <input type="checkbox"/> Marketing <input type="checkbox"/> Other Event Description: <input type="checkbox"/> Adverse reaction <input type="checkbox"/> Adverse event <input type="checkbox"/> Adverse experience <input type="checkbox"/> Adverse finding <input type="checkbox"/> Adverse symptom <input type="checkbox"/> Adverse toxic effect <input type="checkbox"/> Other Date of Occurrence: <input type="text" value="1/1/1950"/> Severity: <input type="text" value="Mild"/> Event Number: <input type="text" value="1111950"/> Description of Adverse Event: <input type="text" value="very mild"/>	
Event Details: <input type="checkbox"/> Death <input type="checkbox"/> Patient died/patient died <input type="checkbox"/> Life threatening illness <input type="checkbox"/> Resulted in significant disability <input type="checkbox"/> Resulted in permanent disability <input type="checkbox"/> Laboratory toxicity <input type="checkbox"/> Assessed as serious by the clinician <input type="checkbox"/> Prolongation of hospitalization <input type="checkbox"/> Required hospitalization and number of days of hospitalization: <input type="checkbox"/> Others	
Reporting: <input type="checkbox"/> Standard <input type="checkbox"/> Expedited	

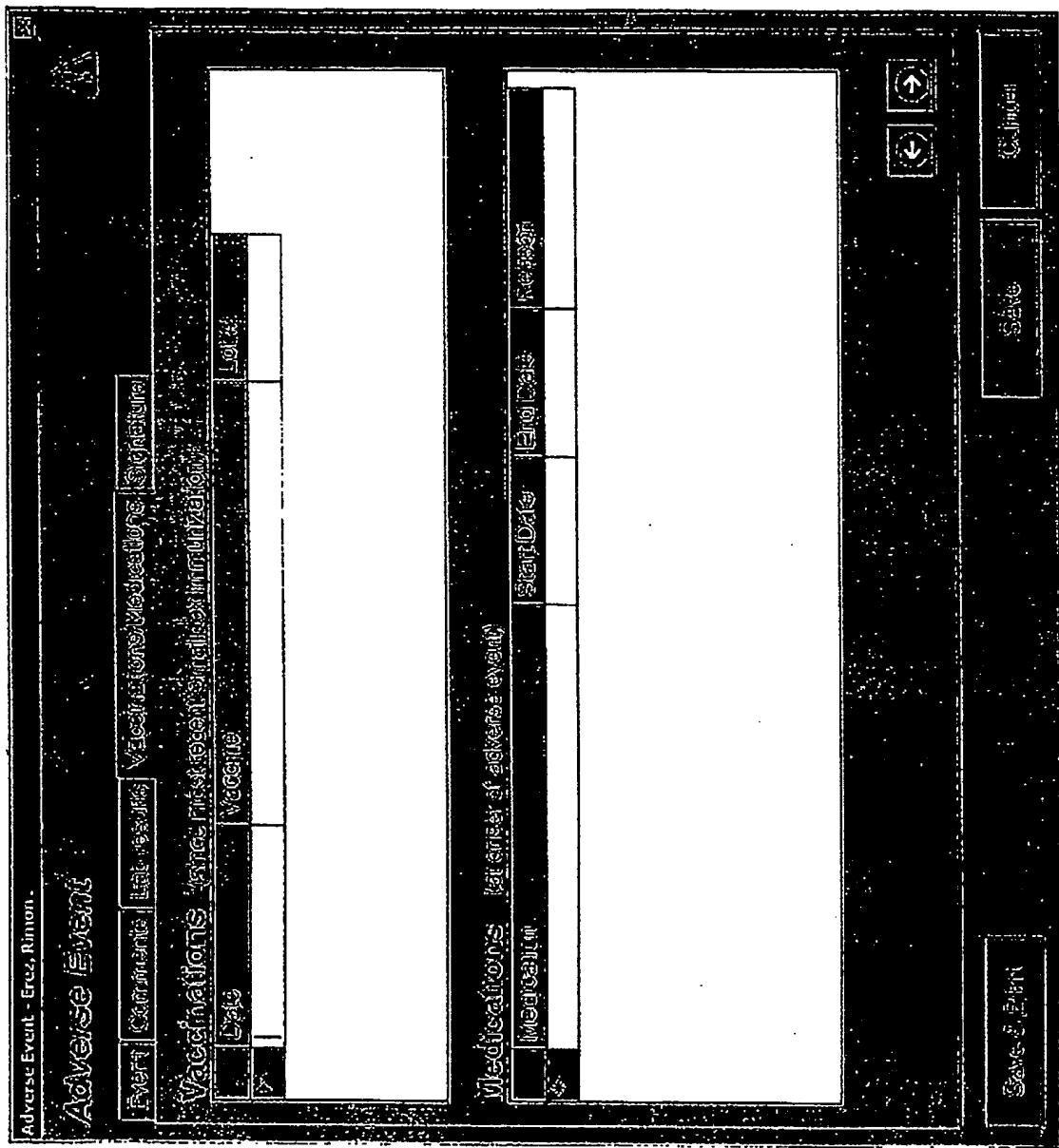
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FIGURE 25



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FIGURE 24

Adverse Event - Free, Runon.																		
Active/Control Trial		Comparison																
Event ID: 1234567890 Version: 1.0 Date: 2023-10-15 Status: Pending Review		Event ID: 1234567890 Version: 1.0 Date: 2023-10-15 Status: Pending Review																
<p>Relevant Clinical Trial Information: This document contains information about a clinical trial involving a new drug candidate. The trial is currently enrolling participants across multiple sites. The primary outcome measure is the reduction in systolic blood pressure over 12 weeks.</p> <p>Demographic Data:</p> <table border="1"> <thead> <tr> <th>Characteristic</th> <th>Active Group</th> <th>Control Group</th> </tr> </thead> <tbody> <tr> <td>Age (years)</td> <td>18-65</td> <td>18-65</td> </tr> <tr> <td>Gender</td> <td>Both genders</td> <td>Both genders</td> </tr> <tr> <td>Race</td> <td>All races</td> <td>All races</td> </tr> <tr> <td>Sex</td> <td>Both sexes</td> <td>Both sexes</td> </tr> </tbody> </table> <p>Primary Outcome: Reduction in Systolic Blood Pressure (mm Hg) at Week 12</p> <p>Secondary Outcomes: Change in Diastolic Blood Pressure, Change in Heart Rate, Change in Blood Glucose Levels, Adverse Events, Safety Profile.</p>				Characteristic	Active Group	Control Group	Age (years)	18-65	18-65	Gender	Both genders	Both genders	Race	All races	All races	Sex	Both sexes	Both sexes
Characteristic	Active Group	Control Group																
Age (years)	18-65	18-65																
Gender	Both genders	Both genders																
Race	All races	All races																
Sex	Both sexes	Both sexes																
<p>Randomization: Participants are assigned to either the Active Group or the Control Group using a random number generator. The randomization process is blinded to ensure fairness.</p> <table border="1"> <thead> <tr> <th>Group</th> <th>Number of Participants</th> <th>Allocation Ratio</th> </tr> </thead> <tbody> <tr> <td>Active Group</td> <td>100</td> <td>1:1</td> </tr> <tr> <td>Control Group</td> <td>100</td> <td>1:1</td> </tr> </tbody> </table> <p>Interventions:</p> <ul style="list-style-type: none"> Active Group: Participants receive the study drug (A123) once daily for 12 weeks. Control Group: Participants receive a placebo once daily for 12 weeks. <p>Adverse Events: All adverse events reported by participants are tracked and monitored for potential side effects.</p>				Group	Number of Participants	Allocation Ratio	Active Group	100	1:1	Control Group	100	1:1						
Group	Number of Participants	Allocation Ratio																
Active Group	100	1:1																
Control Group	100	1:1																
<p>Sample Size: The trial aims to recruit a total of 200 participants across 10 sites. The sample size is determined based on statistical power and significance levels.</p> <p>Recruitment Status: The trial is currently enrolling participants. The recruitment period is expected to last approximately 6 months.</p> <p>Study Duration: The study duration is 12 weeks for all participants, including a 4-week run-in period and an 8-week treatment period.</p>																		
<p>Statistical Analysis: The primary analysis will be performed using an intention-to-treat approach. The primary outcome will be analyzed using a paired t-test. Secondary outcomes will be analyzed using ANOVA or appropriate statistical methods.</p>																		
<p>Conclusion: The trial is designed to provide valuable insights into the efficacy and safety of the study drug compared to a placebo. The results will be published in a peer-reviewed journal and presented at major medical conferences.</p>																		

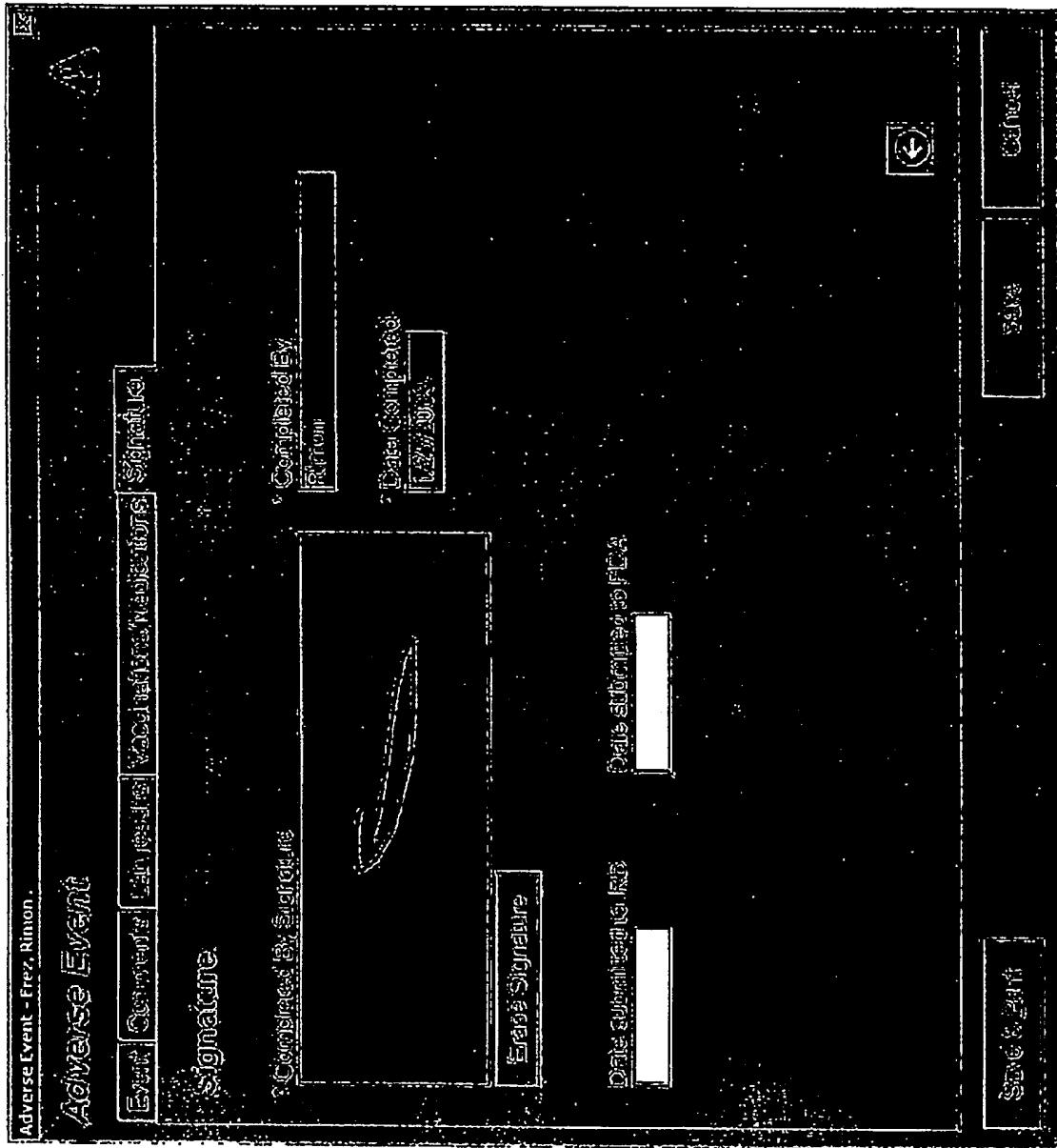
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FIGURE 27



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Configuration

Configure Application Settings

Database | Camera | Vaccine Inventory | Vaccine Exemptions

Vaccine and Dose Inventory

Lot#	Received	Manufacturer	Expires
2	1/1/1900	ACAM1000 (Acam)	1/1/1900
1	1/1/2007	ACAM1000 (Acam)	1/1/1900
*			

Save Cancel

FIGURE 28

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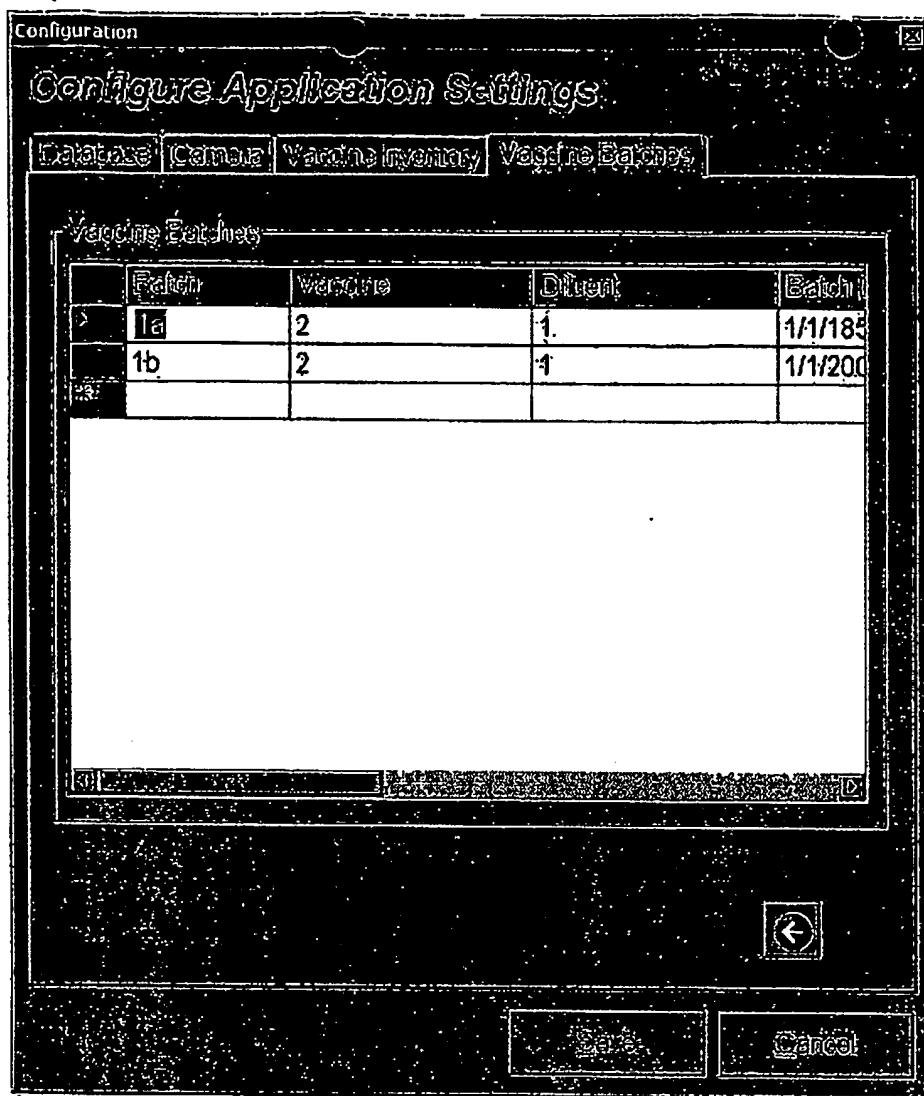


FIGURE 29

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